WP 1.2.1

Manual of Procedures

GA²LEN SURVEY FOLLOW UP

Final Version 2.0 from 01/08/08

Introduction to this document

This document is a Manual of Procedures for partner centres undertaking the GA^{2}LEN Survey Follow up training, part of the activities of Work Package 1.2. This manual is intended to serve as a training and reference documents for study personnel at each GA^{2}LEN centres. It contains details of Standard Operating Procedures for all aspects of study set-up, data collection and data management.

Although the centre staff who will be undertaking the project should be familiar with the procedures detailed in this manual, the guidelines may be useful for new GA²LEN staff which may be appointed as study co-ordinators.

The scientific study proposal is in a separate document "GA²LEN Survey Follow up Protocol" posted on the appropriate project Web page for the Work Package 1.2 - Research Integration.

Centres will be kept informed of any changes made to this document and its appendices. New versions will be emailed to all the stakeholders and posted on the Survey Web pages on the GA^{2}LEN website.

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Section1. Overview

The GA²LEN Survey Follow up is a case-reference study based on a simple general population random sample recruited from respondents to the GA^{2}LEN Survey.

The primary objective of this study is to continue to develop integrated tools for European research and to improve the expertise on clinical and epidemiological research across the GA^{2}LEN network.

The study will establish a European cohort of adults, well phenotyped for allergic disease and linked to a serum bank / DNA bank which will act as a platform for further European studies by the partners on different aspects of allergy and asthma.

The scientific objectives aim to fill in some gaps related to:

- The burden of allergic diseases in European population focusing on the aging population
- The association of severe asthma with potential risk factors (e.g.; chronic sinusitis) and their impact on lung function decline over time
- The association of asthma severity with sex hormone levels; particularly in women after the menopause
- The association of asthma severity and chronic sinusitis with production of IgE to S. aureus in the general population
- The association of asthma and atopic conditions of interest with dietary patterns in the general population
- The association of asthma and other atopic conditions with occupational exposure to cleaning agents and the clinical environment

The study will be important support for the network objectives for building up the capacity to undertake integrated research and determine the capacity of GA^{2}LEN partners to undertake large epidemiological and clinical studies.

The study will give the opportunity for partners to boost the experience achieved so far:

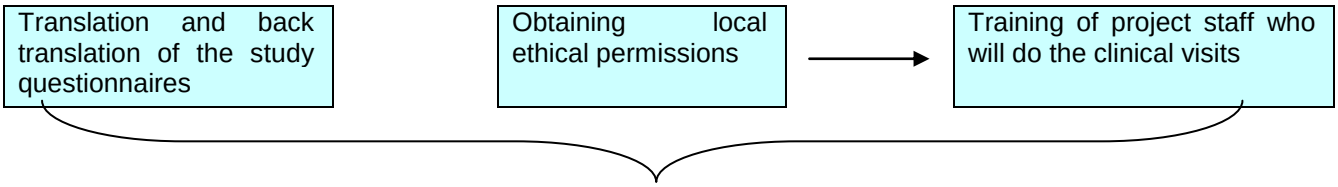
- Development of common study protocols and SOPs
- Delivery of central training in standard methodology
- Adequate translation of common questionnaires
- Application for and granting of local permissions/ethical approvals
- Drawing of adequate cases and referents as per definition
- Standard administration of common clinical questionnaires
- Performance of standard tests following common protocols for lung function, Skin Prick Test, smell test, PNIF
- Standard collection of bloods for serology and creation of a common serumbank / DNA bank
- Implementation of quality control measures for clinical and epidemiological research
- Submission of high quality data for central analysis

This Manual of Operations (MOP) provides instructions to allow all centres to implement the standardised methods consistently. Adherence to the Standard Operating Procedures (SOP) is paramount. In all the aspects of the work standardisation across all centres is vital to ensure high quality data and full integration of our activities.

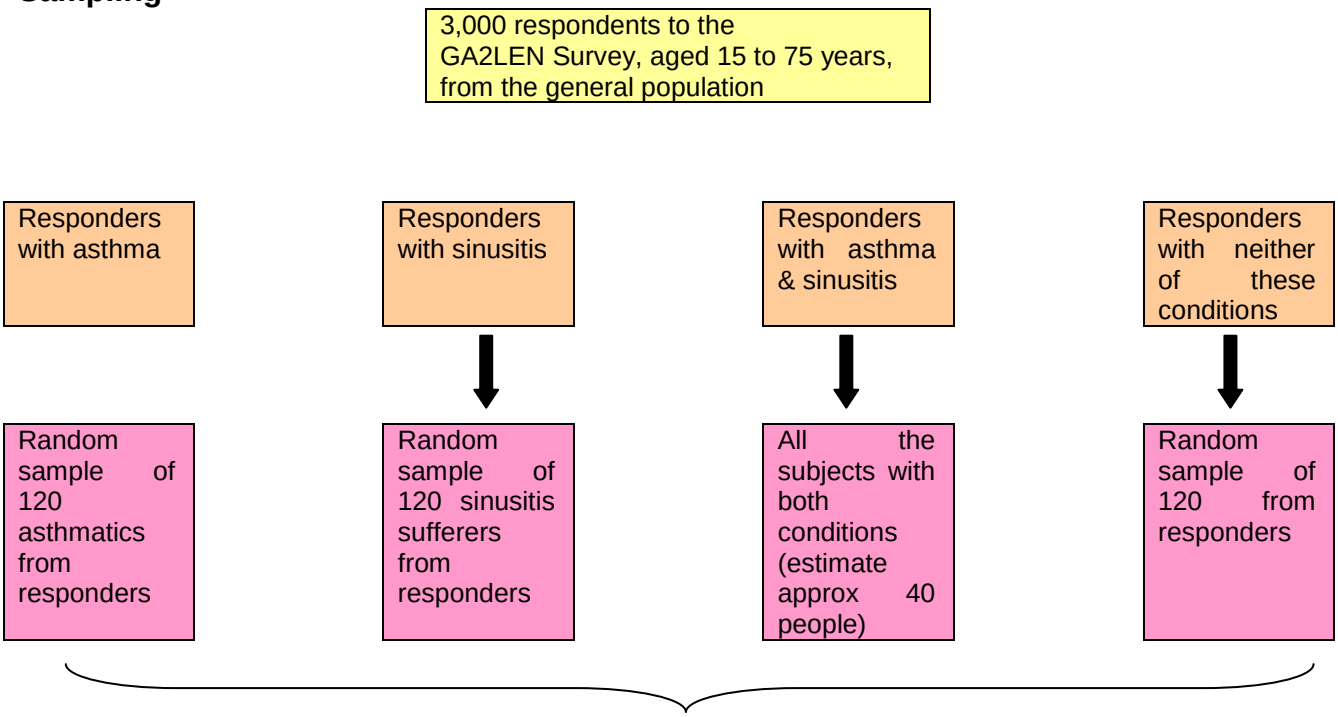
Study methods include three distinct stages. The first is the study preparation: translation of study questionnaires into local languages, granting local ethical approvals and completion of central training in study methodology. The second stage is identification of adequate cases and referents from respondents to the GA^{2}LEN Survey. The third stage is the collection of further data from this sample and data analysis. Section 2 below shows a flowchart of the study.

Section 2 GA²LEN Survey Follow Up Flow chart

Preparatory Stage


Translation and back translation of the study questionnaires
Obtaining local ethical permissions
Training of project staff who will do the clinical visits

Sampling


3,000 respondents to the GA2LEN Survey, aged 15 to 75 years, from the general population
Responders with asthma
Responders with sinusitis
Responders with asthma & sinusitis
Responders with neither of these conditions
Random sample of 120 asthmatics from responders
Random sample of 120 sinusitis sufferers from responders
All the subjects with both conditions (estimate approx 40 people)
Random sample of 120 from responders

Clinical Visit – Data Collection

- Obtaining Written Informed Consent
- Height, weight, waist/hip circumference measurements
- PNIF
- Smell test
- Lung Function Tests (FEV with reversibility)
- Face-to-face questionnaire administration
- Serology (Total IgE, Grass IgE, Superantigen IgE to S. aureus mix, sex hormones)
- Skin Prick Test (the GA^{2}LEN panel of 14 allergens, including histamine and dilutant controls)

Data entry and Transfer

- Double data entry for 280 cases and 120 controls per centre
- Data transfer
- Central analysis

Section 3 Questionnaire Translation

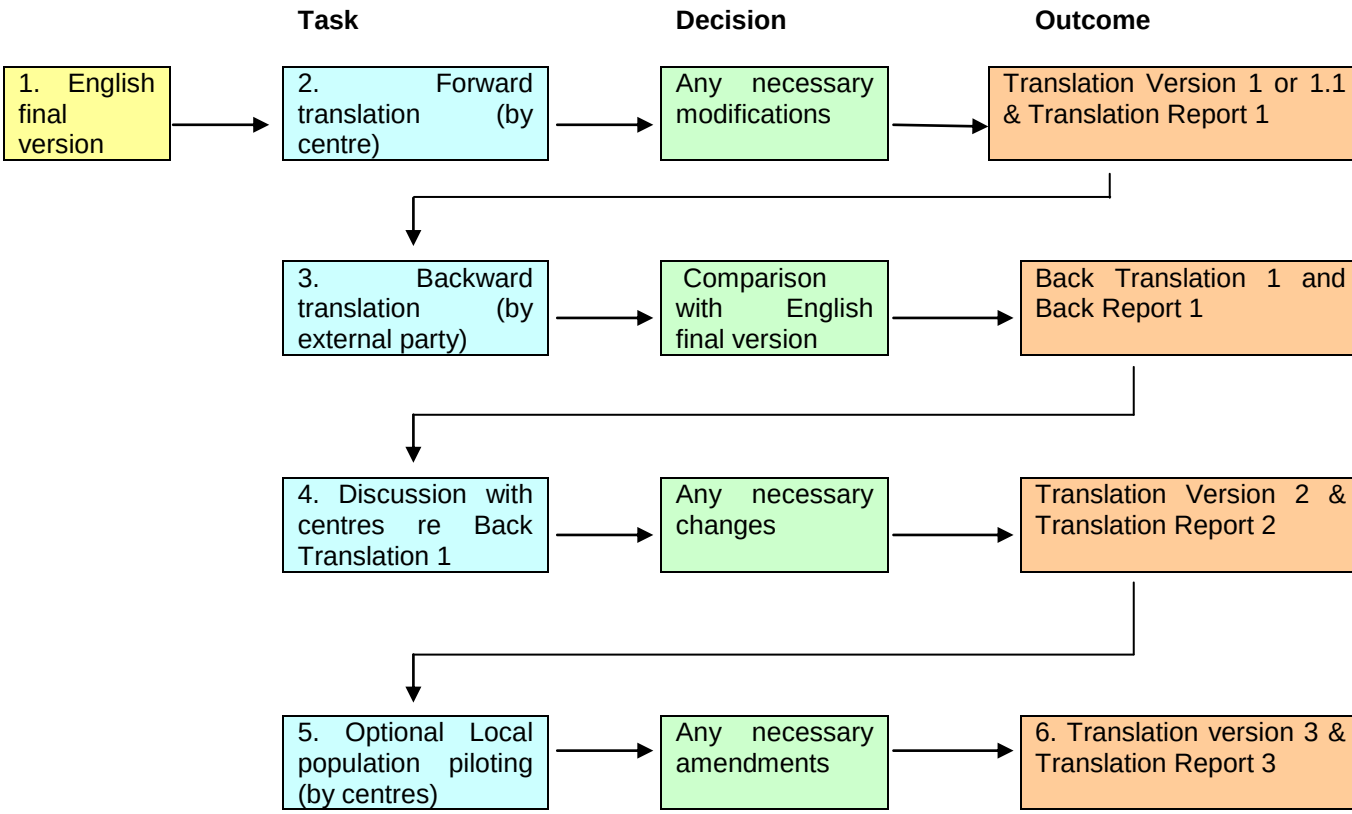
Standardised Operational Procedures

Most centres will wish to translate the study questionnaires (from UK English) into a locally appropriate language. In order to ensure the integrity of study questionnaires the document translation Standardised Operational Procedures (SOP) must be observed. Standardised translation procedures will ensure that all centres collect the same data. The translation protocol will be used for the GA²LEN Follow Up Study Questionnaire, Women's Questionnaire and Food Frequency Questionnaire but not necessarily for any other source documents, including SOPs and instructions for administering the Questionnaire. These documents can be translated at centres' discretion.

Questionnaire translation incorporates 3 main stages – these are shown in the flow chart below and then described in further detail.

- forward translation (from English into local language(s))
- backward translation (comparison and any necessary editing)
- optional local population testing (including subjects with asthma, and/or allergies, and/or sinusitis, and/or rhinitis)

Flow chart of the translation process


Task
Decision
Outcome
1. English final version
2. Forward translation (by centre)
Any necessary modifications
Translation Version 1 or 1.1 & Translation Report 1
3. Backward translation (by external party)
Comparison with English final version
Back Translation 1 and Back Report 1
4. Discussion with centres re Back Translation 1
Any necessary changes
Translation Version 2 & Translation Report 2
5. Optional Local population piloting (by centres)
Any necessary amendments
6. Translation version 3 & Translation Report 3

3.1. English final versions

The English final version of the GA²LEN Follow Up Study Questionnaire is the source document. It is written in UK English and will be provided by the co-ordinating centre as a Word document or as a hard copy document. There have been some draft versions of this document made available before the final version, but **only the document titled "GA²LEN Follow Up Study Questionnaire English Final" (Version 2 from 01-08-08) should be considered the translation source.**

3.2 Forward translation

Translation of source documents should follow the procedure below:

- Recruit a local translator (native target language and bilingual UK English). This could be a member of the study team.

- The translator produces 'Translation version 1' (including questions and response choices). This should be a conceptual equivalent of the English final version document, in colloquial language and easy to understand.

- **Important note**: The questionnaire contains standard questions used in previous studies (ECRHS, GA²LEN Survey, etc). They have been already translated into local languages so please use the existing standard translations and copy the exact wording. This will allow comparability between studies and centres and will also save time and money!

- If local centre staff (with or without the translator) assess that 'Translation version 1' needs modification then 'Translation version 1.1' incorporating any changes should be produced.

- The translated documents should be in editable electronic formats compatible with Microsoft Word.

- Centre staff should produce Translation report 1 which should describe how the translation was produced and outline (question by question) any issues that have arisen so far.

- Please email Translation version 1, Translation version 1.1 (if appropriate) and Translation report 1 to the co-ordinating centre to m.lim@imperial.ac.uk

3.3 Back translation

Back translation is a requirement for the study documents: Ga2len Survey Follow Up Main Questionnaire, Women's Questionnaire and the Food Frequency Questionnaire.

- Centres are asked to arrange for back translation which must be undertaken by a different person and someone completely unrelated to the work of the centre. They should not have specialist knowledge of asthma, allergies, rhinitis, sinusitis, skin allergies or survey work.

- The back translator should not have access to the original English final version while producing the translated questionnaire in English 'Back translation 1'.

- Centres are asked to compare Back translation 1 with the English final version and produce Back report 1 identifying any misunderstandings or inaccuracies in Translation version 1 (or Translation version 1.1). Back report 1 should also state the main occupation of the back translator.

- Please send Back translation 1 and Back report 1 of the Main Questionnaire to: **m.tumilty@imperial.ac.uk;** Women's Questionnaire to: **d.jarvis@imperial.ac.uk** and finally the Food Frequency Questionnaire to: **v.garcialarsen@imperial.ac.uk**

3.4 Discussion

- Co-ordinating centre staff will confer with centre staff (if possible the forward translator) to negotiate changes to Translation version 1 (or 1.1).

- Following these discussions the centre should produce Translation version 2 and Translation report 2. Translation report 2 should be in English and should detail the changes made to Translation version 1 (1.1) with the preferred target language expressions and their English equivalents.

3.5 Local Pilot

- This step is optional, although it is strongly recommended that Translation version 2 is tested in at least 5 local and 'naive' participants in order to ensure it that final translated versions will capture the required information in the target population. Piloting is strongly recommended for centres which have never been part of GA^{2}LEN common studies and where existing translation of standard questions in the local language does not exist.

- Translation version 2 should be used in face-to-face interviews with local participants, men and women, within the study age range. The participant panel should include at least 5 subjects with asthma, and/or allergies, and/or rhinitis, and/or sinusitis. The main goal of the pilot is to see if the participants understand the questionnaire in the way intended by researchers.

- Translation version 2 questionnaires should be administered by staff experienced in research questionnaire administration. The interviewer should monitor if the participant has any difficulties understanding any of the questions and check the participants' interpretation of all items. If any queries arise, the interviewer may test alternative translations of the problem item or ask to participant to suggest an alternative.

- If the centre wishes to implement changes following piloting, it should submit translation report 3 to the co-ordinating centre. Report 3 should outline the pilot method and population. It should detail any problems encountered and describe any changes present in translation version 3. Translation version 3 should be proof read and then submitted to the co-ordinating centre.

3.6. Producing Translation version 3

If step 3.5 'local pilot', is not observed **Translation version 2 should be proof read and submitted to the co-ordinating centre as Translation version 3.** Following submission of 'Questionnaire Translation version 3' centres may then make copies and use them in the GA²LEN Survey Follow Up Study. **No data entry should commence until translated data entry systems have been created and tested.**

Section 4 Local permissions

The requirements for local permissions to carry out the GA²LEN Survey Follow up may vary between centres. There are nonetheless some standards that must be met by all centres before the start of data collection.

4.1 Ethical review

Centres must receive necessary local ethical permissions to carry out the study in the target population. This will normally involve review of the protocol, study documents and participant documents by a human subjects review panel, institutional review board or local ethics committee. For this study, the Ethics Committee (EC) may be the one attached to the University or Hospital you are affiliated with. Due to the new legislation and the Human Tissue Act, centres should mention in their applications with ethics that samples will be **stored indefinitely**, may be **part of a European serum bank / DNA bank**, **may be shipped outside the country (but not outside the EEA) for future analyses**, **may be given to other researchers within the network, for other projects which will always have ethical approval** and **other analyses (than those specified) may be undertaken in completely anonymised samples but we will always seek ethical approval for this.**

Centres must provide the co-ordinating centre with written confirmation that ethical permission has been given before the commencement of the study. When an Institutional Review Board or Ethics Committee grants permission for the study to proceed, centres are asked to deliver a copy of the permission to the coordinating centre.
Electronic versions can be sent to **m.lim@imperial.ac.uk** or uploaded on the centre documents folder on the study website. Hardcopies can be mailed or faxed.

4.2 Informed consent

All study participants must give their **written informed consent** for all aspects of the clinical visit or home visit. Study participants who are unable or unwilling to give written informed consent are ineligible to participate in the study.

4.2.1 Participant Information Sheet

Participants should normally be sent written information about what the study involves so that they can decide properly if they wish to take part. This information should be contained in the "Participant Information Sheet" (Appendix 7). This document should be written in easy to understand colloquial language of the target population and meet the following criteria:

- The information sheet should have a clear and unambiguous heading
- The duration of the study
- The language must be easy to understand
- It should explain that the study is a research study, taking place in many European countries
- It should explain what will happen if the participant takes part
- It should state that the visit will involve giving blood sample and that the sample will be considered a donation/gift from participant.
- It should explain that blood samples (separated from the participant's personal details) will be stored for later analysis
- It should explain that genetic material in the blood sample may be analysed in the future, but only for research into asthma and allergy and for no other purpose
- It should state any financial involvement
- It should state that all information shared with study staff will be kept confidential and that personal details will be separated from the collected data
- It should explain that the collected data will be stored in encrypted format
- Any possible risks / benefits of taking part must be listed
- It should explain what information the participant may receive after the visit
- Information should be given describing what will happen if something goes wrong at the visit. Any compensation arrangements should be detailed
- It should explain what will happen to the results of the study
- It should state who is funding the research
- It should state who has given ethical approval for the study
- It should state a contact for further information

An English sample of the Participant Information Sheet is provided (Appendix 7). Centres must keep a copy of their locally approved Participant Information Sheet filed with other study documents and Version and date should be stated. The Participant Information Sheet should be posted to participants before their visit, so they can have time for consideration before giving written consent at the visit.

4.2.2 Consent form

A sample study consent form is provided (Appendix 8) but this may also need local editing to meet the requirements of centres' Institutional Review/ Ethics Board/Ethics Committee. As with the information sheet, centres must keep a copy of the locally approved consent form filed with other study documents. Written consent will be obtained at the visit, before measurements and interview starts. Adult participants will have to consent their participation. However, adolescents under the legal age of consent, parents or legal representative will have to give their consent for their participation.

The consent form should refer to the correct version number and date of the Participant Information Sheet that the participant has been given. It should reiterate that the study blood sample is given as a donation. It should clearly state that the participant gives their permission that his or her blood sample and **the genetic material in the sample** may be analysed in the future, on a number of occasions, as part of research in asthma and allergy (and not used for any other purpose).

4.2.3 Obtaining Consent

Before consent is obtained participants must be given ample time based on EU GCP standard (as recommended in EU GCP Directives 2001/20 and 2005/28); to decide if they wish to participate or not. All study subjects must provide informed consent for all aspects of the clinic visit. **Written Consent** must be obtained before the clinical visit starts. It is not permissible to obtain consent from a guardian / third party. However, for adolescents under the legal age of consent, parents, or the legal representative of the child, must consent for them.

Consent should be obtained by a trained study staff member, in a private and quiet location so that the participant can ask questions freely. To avoid pressuring the participant only one member of study staff should be present during the consent process. If the participant is uncertain and hesitating, longer time for consideration should be given and the visit should be re-booked after the subject is certain he/she wants to take part.

Some local Ethics or Review Committees may require that the participant be given a copy of their signed and witnessed consent.
If the centre has an approved process for obtaining oral consent, this is permitted **as long as the local Review or Ethics Committee has agreed to this in writing.**

4.3 Confidentiality

Participants' data must be kept confidential.

- Each study participant must be assigned a unique ID number by centre (from within the allocated ID number range). This will be in fact the number already allocated during the GA^{2}LEN Survey (Appendix 9).
- Study ID numbers that relate to any personal data (names and addresses) must be kept separated from any ID numbers attached to data collected during the clinical visit.
- Computers should be password protected and data should be stored in encrypted format
- No personal data (names and addresses) should ever be transferred out of centres. Transferred data should be identified by unique subject ID, sample ID and centre ID **only.**
- Transfer of data between centres and the co-ordinating centre will be made electronically by secure file transfer
- Centres should keep all study forms, hard copies of data collected during the clinical visit data and other confidential information in secure locked areas. While in use, such forms should be kept private and safe as a priority
- Study participants may not be identified by name or any other means in any report, publication or presentation

Section 5 Sampling

5.1 Target population

Participating participants to this study are responders to the GA^{2}LEN Survey who consented to "further contact". This is a representative general population sample of subjects aged 15 to 75 years of age, living within an existing administrative area of at least 150,000 inhabitants, who presumably reported no disease at all, or reported having asthma and/or at least one of the other conditions of interest (chronic sinusitis, eczema, drug allergies, rhinitis, etc). It is therefore implied that each participating centre has already a list of up to 3,500 potential participants who returned a completed GA^{2}LEN Survey questionnaire and gave consent to be contacted for further research.

The sampling methodology of the follow up participants from this existing cohort is explained below.

5.2 Sampling

1. A random sample **of asthma and sinusitis cases** from the GA^{2}LEN survey respondents will be drawn by the coordinating centre for each respective centre, until at least 120 cases of asthma and 120 cases of sinusitis (resulting in a total of 240 subjects).

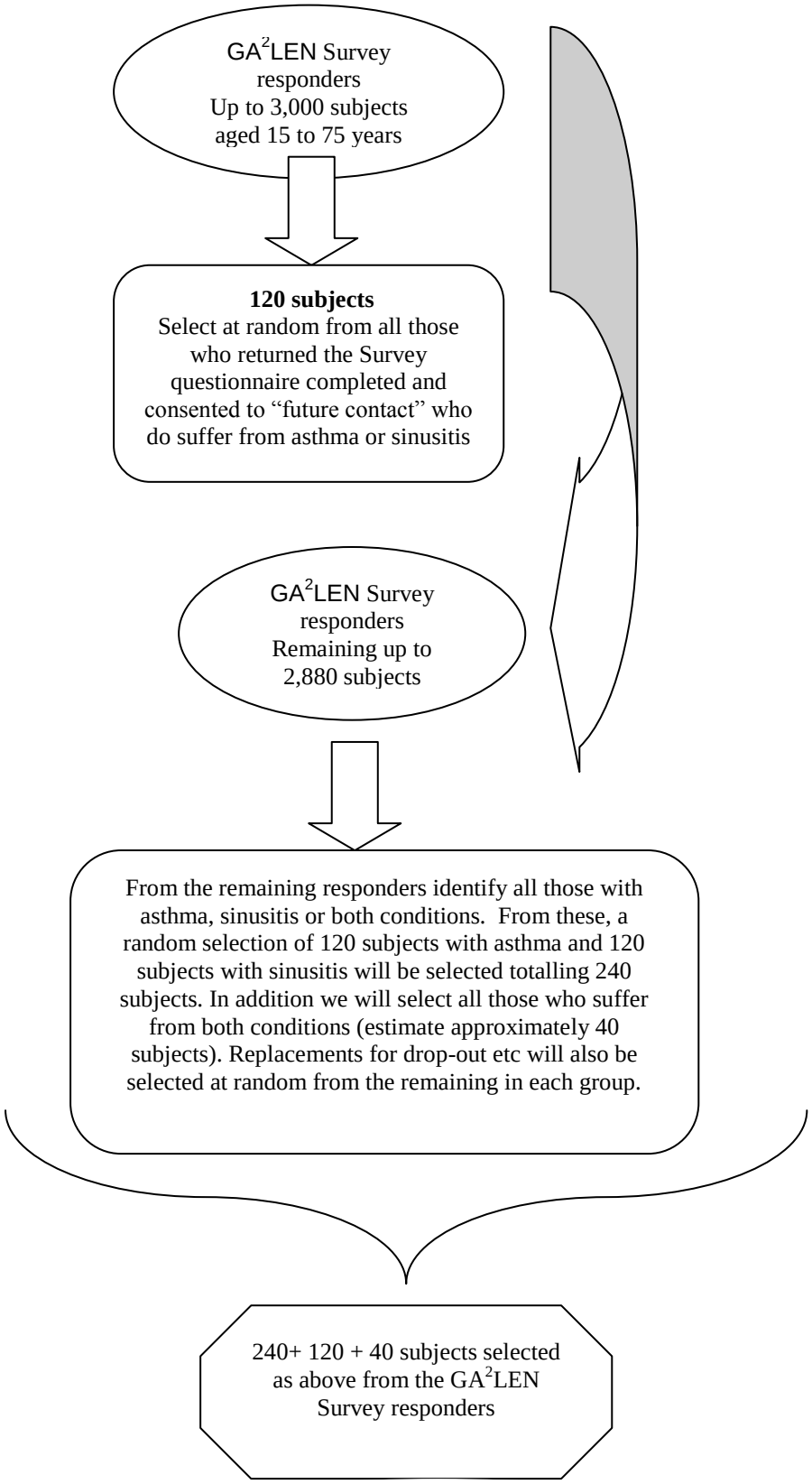
2. A random sample of 120 of the GA^{2}LEN Survey responders who consented to be contacted for "future research" and who do not suffer from asthma or sinusitis will be drawn by the coordinating centre for each respective centre.

3. In addition, it is anticipated that approximately 40 individuals who suffer from both asthma and sinusitis will also be selected to be included in the study.

Please refer to diagram below for clarification!

Each centre's sampling strategy should be discussed again with the co-ordinating centre before implementation.

5.3 Definition of sample plan and referents


GA²LEN Survey responders
Up to 3,000 subjects aged 15 to 75 years
120 subjects
Select at random from all those who returned the Survey questionnaire completed and consented to "future contact" who do suffer from asthma or sinusitis
GA²LEN Survey responders
Remaining up to 2,880 subjects
From the remaining responders identify all those with asthma, sinusitis or both conditions. From these, a random selection of 120 subjects with asthma and 120 subjects with sinusitis will be selected totalling 240 subjects. In addition we will select all those who suffer from both conditions (estimate approximately 40 subjects). Replacements for drop-out etc will also be selected at random from the remaining in each group.
240+ 120 + 40 subjects selected as above from the GA²LEN Survey responders

This is your follow up sample!!

5.4 Preparation of Study Master Files

These files will be used for the electronic storage of data. Each centre should create two different files:

- Study Master file: name, address, date of birth, sex, study ID, sampling code and the essential study documents
- Transfer Master file: study ID, sex, date of birth, sampling code

5.4.1 Study Master File

This file should contain: Name, Address, Date of birth, Sex, Participant Study ID, sampling code and the Essential Study Documents.
This file should be stored in encrypted format in the local computer and it will never be transferred out of centre, due to confidentiality issues.

5.4.2 Transfer Master File

This file should contain: **Participant Study ID, Date of birth, Sex and sampling code.**

Only this file can be transferred to the co-ordinating centre via secure GA²LEN website folders as it does not contains participants' personal data. The co-ordinating centre will provide an Excel spreadsheet Transfer Master File template.

Section 6 Study Recruitment Process

6.1 Invitation and appointment

400 subjects from those who have returned a completed GA^{2}LEN survey questionnaire and have agreed to be 'contacted further' have now been selected. The next step is the invitation of these 'potential participants' to take part to the follow up study. Each centre may have their most appropriate local recruitment method for the study.

Scenario 1

Once selected, each potential participant would be contacted via telephone and invited to take part in the follow up study. This implies you have asked for their contact details including phone number, during the GA^{2}LEN Survey. Short and convincing details of the study aim, research institution, ethical approval granted and what the clinical visit will imply needs to be given. If the subject agrees to take part, an appointment should be booked **immediately**, mentioning that detailed written information will be posted together with a confirmation of appointment letter and directions for reaching the clinic. The Food Frequency Questionnaire (FFQ) (appendix 20) will be included in this mail out and participants will be asked to complete it the day before the visit **(24 hours before the visit)** and bring it to the clinic. It is it is very important to ensure that study staff who will be responsible for stuffing the envelopes match the correct ID labelled Food Frequency Questionnaire to the correct addressed appointment letter.

Every female that is recruited into this study must be asked to complete a blank women's questionnaire (Appendix 22) for them to complete the day of the visit **(AFTER THE MAIN ASSESMENT HAS BEEN CONDUCTED).** This completed questionnaire should then be returned to the study staff either while the participant is still in the assessment area, or via a pre paid envelope. It is therefore very important to ensure study staff match the correct ID label to the Women's Questionnaire.

Below is a list of materials to be used for this scenario.

Materials	Description	Numbers required
Total Appointment Letters	A4 single sided sheet	400
Total Participant Invitation Sheet	A4 double sided single sheet	400
Total Participant Information sheets	A4 double sided x2 pages	400
Total FFQs	4X 2 sided A3 pages, colour, brochure	400
Women's questionnaire	4X 2 sided A3 pages, colour, brochure	200
Total ID stickers	One per FFQ questionnaire	400
Total mail-out envelopes with address window	C5 with return address 'if undelivered' marked in small print	400
Total maps and directions to the visit venue	A4 double sided single sheet	400

Reminder of appointment: One day before the appointment, you need to telephone the participant and remind them that the visit will take place "tomorrow" and the time of the appointment. Ideally, the research nurse who will be doing the clinical visit will ring the participant, so a contact can already be established prior to the visit. This is important for the participants! This call should be used to make sure that participants are reminded to complete the Food Frequency Questionnaire (FFQ) at home and bring it to the clinic next day.

Scenario 2

Another possible way of inviting people and booking appointments is by sending a postal invitation involving one initial mail-out to the sample, followed by up to 2 reminders to non-responders and separate mail out for confirmation of appointment.

An invitation letter, a Participant Information Sheet and a Reply Sheet asking for Contact details (including phone number) needs to be posted at this stage.

Below is detailed information of the mail-outs and necessary material.

Mail-out I Invitation: this mail-out is to the entire drawn sample
400 unique IDs, 400 addresses
Invitation Letter
Participant Information Sheet
Contact Reply Sheet (name, address, phone number)
C5 envelopes with address window
ID stickers for label of Contact Reply Sheet
Pre-paid reply envelopes
Stuff the mail-out I envelopes with the mentioned items. **Post all 400 envelopes on the same day.**
Monitor the response to mail-out 1 daily.
Allow 2 weeks between the posting day of mail-out I and the posting day of mail-out II.

Mail-out II Invitation: this is a reminder to all the non-responders of mail-out I, after 2 weeks.
(For example) 200 IDs, 200 addresses
Before carrying out mail-out II, review mail-out 1 response. Only those who have not responded to mail-out I during the 2-week gap should be mailed a second time.
Invitation Letter
Participant Information Sheet
Contact Reply Sheet (name, address, phone number)
C5 envelopes with address window
ID stickers for label of Contact Reply Sheet
Pre-paid reply envelopes
Stuff the mail-out II envelopes with the mentioned items. **Post all 200 envelopes on the same day.**
Monitor the response to mail-out II daily.

Allow 2 weeks between the posting day of mail-out II and the posting day of mail-out III.

Mail-out III Invitation: this is a reminder to all the non-responders of mail-out II following 2 weeks
(For example) 100 IDs, 100 addresses
Allow 2 weeks between the posting day of mail-out II and the posting day of the final mail-out III
Before mail-out III review, mail-out I & II responses. Only those who have not responded to mail-out I or II during the 4-week gap should be mailed a third time.
Invitation Letter
Participant Information Sheet
Contact Reply Sheet (name, address, phone number)
C5 envelopes with address window
ID stickers for label of Contact Reply Sheet
Pre-paid reply envelopes
Stuff the mail-out I envelopes with the mentioned items. **Post all 100 envelopes on the same day.**
Monitor the response to mail-out III daily.

Materials
Below is a list of materials required for 3 mail-outs. Example amounts are given. The exact numbers required will depend on the response to the first 2 mail-outs. Of course not everyone whom you mail will respond positively, or indeed respond at all. It may be that you are required to mail to 800 or more individuals to recruit sufficient numbers of subjects in each strata for the study requirements.

Materials	Description	Numbers required
Total Invitation Letters	A4 single sided sheet	700
Total Participant Information Sheets	A4 double sided x2 pages	700
Total Contact Reply Sheets	A4 single sided sheet	700
Total ID stickers	One per Contact reply sheet	700
Total C5 envelopes with address window	C5 with return address 'if undelivered' marked in small print	700
Total pre-paid reply envelopes	C5 Pre-addressed (+ pre-franked if possible)	700
*Units for mail-out I		400
*Units for mail-out II		200
*Units for mail-out III		100

*I unit =Invitation Letter + Participant Information Sheet + Contact Reply Sheet + ID sticker + franked reply paid envelope + mail-out envelope

6.2 Appointment of participants

Once you have posted the Invitation to take part in the clinical visit, it is expected that those who have read the Information Sheet and are still willing to take part, will send you back the Contact Reply Sheet, giving you details on their name, address and phone number. You need to check that the respondent is the same person who answered the GA^{2}LEN Survey questionnaire, by checking the ID sticker on the reply sheet and the details of the screening survey responders. This will ensure that people who reply are the same as those selected from the GA^{2}LEN survey and therefore, they meet the inclusion criteria for the follow up study.

As soon as the Contact Reply Sheet is received, you need to process their information into your database. Then phone the person and **book an appointment** for the clinical visit. As soon as this is done, a letter confirming the day and the time of the appointment, together with directions and map of the visit venue should be posted to the participant. The Food Frequency Questionnaire (appendix 20) will be included at this stage with the specification that **these need to be completed the day before the visit** and each participant needs to bring them to the clinic. **It is very important to ensure that study staff who will be responsible for stuffing the envelopes match the correct ID labelled Food Frequency Questionnaire to the correct addressed appointment letter.**

6.3 Recording

Each individual invited to take part in the follow up (400 subjects) should be accounted for with a response code. Individuals who return a completed questionnaire I are called 'responders' and must be coded '1'. The point at which an individual was defined as a 'non-responder', for example, if an individual has not returned questionnaire I more than 2 weeks after mail-out III, may be defined locally. Reasons for non-response should be determined and coded. There are 4 non-response codes:

1	**Responded**_____	Returned completed Contact Reply Sheet
2	**Refused**_____	Returned blank Contact Reply Sheet or any kind of refusal
3	**Known to have moved or address unknown**___	Returned unopened invitation letter. Opened letter indicating change o address. Other contact informing of change of address.
4	**No response after 3 mail-outs**_____	No response returned after all 3 mail-outs
5	**Other (e.g. deceased, overseas, language_____ difficulties)**	Letter is returned or other contact is made indicating that the participatior cannot be confirmed, etc

The ability to record response code 3 may vary between centres. To maximise the use of this code, a 'return address if undelivered' must be marked on the outside of the outward envelope and the local postal system must be able to accommodate the return of undelivered mail.

6.4 Materials

Below is a list of materials required for confirmation of appointment. You will require more materials than you anticipate. This is why we have accounted for 500 examples of each even though you will only see 400 participants.EG people will make appointments, but fail to turn up.

Materials	Description	Numbers required
Total Appointment Confirmation Letters	A4 single sided sheet	500
Total FFQs	4X 2 sided A3 pages, colour, brochure	500
Total ID stickers	One per FFQ questionnaire	500
Total Maps and directions	A4 double sided sheet	500
Total C5 envelopes with address window	C5 with return address 'if undelivered' marked in small print	500
Total women's questionnaire		

Reminder of appointment: One day before the appointment, study staff should phone the participant and remind them that the visit will take place "tomorrow" and the time of the appointment. Ideally, the research nurse who will be doing the clinical visit will phone the participant, so a contact can be already established prior visit. This is important for participants! This call should be used to make sure that participants are reminded to complete in the Food Frequency Questionnaire (FFQ) at home and bring it to the clinic next day.

Section 7. Clinical Visit

The following chapters present step by step, the procedures to be followed during the clinical visit, and the order they are scheduled to take place.

7.1 Location of visit

The visit may take place in a clinic, other suitable premises appropriate for clinical procedures, or in the participant's home. A private area should be available to ensure confidentiality and dignity. The most appropriate environment is a private, temperature-controlled room at a central location (such as a local health clinic). All necessary equipment should be available in the room. The room should be well lit, preferably with a window, and located in a quiet area of the clinic. These conditions will improve the quality and reproducibility of the results. For safety, the participant needs to be seated in an armrest chair during spirometry. There must be a couch, clinical trolley or bed available should the participant need to lie down during or after venepuncture. This study is designed to take place in a safe clinical environment. If your centre decides to employ the home visit procedure, please ensure that you have obtained all appropriate equipment, documentation including ethics approval and insurance to do so.

7.2 Equipment

The following items are needed for each clinic visit.

- Questionnaires (or pc containing Epidata form for Questionnaires)
- Questionnaire instructions (appendix 19)
- Inhaled steroid dose table (appendix 5)
- Local reference of steroid inhaler formulations
- Copy of ISCO-88 (ILO) codes (refer to appendix 18)
- Calculator
- Consent forms
- Stadiometer
- Nurses tape for Waist and hip measurement
- Weighing scales (portable wood or plastic surface – for use in carpeted areas)
- ndd EasyOne^{TM} Spirometer
- 3.00 litre calibration syringe
- Spirometry equipment spirettes, nose clips, tissues, timer, chair without wheels, spare AA batteries, Spacers.(Possibly Clement Clark Single-Use Able)
- Skin prick test kit (allergens – kept refrigerated, Allergopharma lancets, timer with alarm, sharps bin, clinical gloves, template, scotch tape, millimetre rule, fine tipped felt pen, antihistamine cream , tissues and waste bin)
- Smell test Kit (12 pens Sniffin' Sticks, multiple choice cards and results record sheet)
- PNIF equipment (In-Check Inspiratory flow meter, Mouthpiece connector, Facemask – size 5)
- Unique bar code ID labels – matching subject's ID (supply by coordinating centre)
- Venepuncture kit (needles, needle holders, serum separator tubes either product 367955 or 367954, EDTA tubes product number 367864, vaccutainer tube rack, 2ml Sarstedt tubes with evaporation proof seal, gloves, sharps bin, receiver, cotton wool, spot plasters, small plastic bag with seal, cool box, washable pillow, blood spill kit)
- Cool box or refrigeration only required where blood collection is >2 hr from the processing laboratory

Centres are asked to acquire all equipment themselves, although some equipment specifications should be met – in particular, PNIF equipment or Sniffin' Sticks Kit, specific blood collection tubes and sample storage tubes should be used (Section 12). Minimum standards are also required for the quality of the stadiometer, weighing scales and calibration syringe.

7.3 Visit task sequence

Where possible, tasks should be undertaken in the sequence listed below.

- Obtain informed consent
- Confirm ID and check sample barcodes
- Measure height, weight, waist and hips
- PNIF
- Smell Test
- Spirometry baseline including administering bronchodilator
- Administer Main Questionnaire
- Repeat spirometry
- Obtain blood samples
- Start skin prick test
- Check self administered questionnaires (FFQ and EuroQOL)
- Record skin prick test results

7.4 Obtaining informed consent

All study subjects must provide informed consent for all aspects of the clinic visit. **Written consent** must be obtained before the start of any study procedure. It is **not** permissible to obtain consent from a guardian / third party. However, for adolescents under the legal age of consent, parents, or the legal representative of the child, must consent for them. Study participants who are unable or unwilling to give written informed consent are not eligible to participate in the study. Centres are asked to store all participant completed consent forms together with their other study documents.

The research nurse should ensure that a private space is available for discussion before obtaining written consent. This will provide the participant with an opportunity to ask questions about their participation in the study. The participant should be asked if he has read and understood the Participant Information Sheet (Appendix 7). Check if an explanation is required regarding the need for written consent. The participant needs to sign two copies of the Consent Form (see Appendix 8); one will be filed with the participant's collected data and one will be given to the participant. If the subject is hesitant about participation, queries should be clarified, and if necessary more time for consideration should be given.

7.5 Confirm participant ID

It is extremely important that all data relating to each subject are properly labelled with the correct unique subject ID. Centres are asked to keep a master file of all subject IDs together with the names, dates of birth and study sample ID code (a database file would be most appropriate). Before each visit, study staff should enter the centre ID (Appendix 9), sample ID and unique subject ID onto the visit forms (questionnaire, skin test results sheet, smell test and PNIF results sheet and consent form) and check it against the master list. The unique ID barcode labels should be checked against the master list and Questionnaire to ensure that the correct ID and the same ID is used for all the subject's data and samples. Name and date of birth should be confirmed by the participant (staff may need to make a note of the name and date of birth on the master list and take it with them to the clinic visit).

7.6 Barcode sample stickers

Unique IDs were assigned by centre from the allocated range (see Appendix 9) during the GA^{2}LEN Survey. At the completion of GA^{2}LEN Survey, each centre is asked to submit an electronic list of the IDs of potential follow up participants to the co-ordinating centre. The list should have been transferred to the relevant centre folder at the SURVEY Follow Up Project Website. The co-ordinating centre will produce adhesive, bar-coded laboratory stickers to be used to label blood and serum samples. The stickers will be of standard format (24x13mm) and must be used to label sample tubes **no smaller than Sarstedt 2ml sample tubes**. The labels will indicate each unique subject ID in normal digits and in a barcode font. The co-ordinating centre will supply hard copy printed laboratory labels with 14 labels per requested ID number. The total number of unique barcode stickers required for each visit may vary for each subject based on how many serum storage tubes are filled after separation by centrifuge. On average one visit will need 13 correct stickers for: 1 EDTA tube, 6 serum 2ml storage tubes; 1 for sample logbook (example in appendix 15), 1 for the Food Frequency Questionnaire, 1 for the Women's Questionnaire, 1 for the Quality of Life questionnaire 1 for the main questionnaire and 1 for the tracking form. It is not necessary to use the barcode stickers to label the serum blood collection tubes that are disposed of after centrifugation.

To minimize costs centres will be sent labels only for the subjects suitable for the clinical visit.

7.7 Measurement of height, weight, waist/Hip circumference

Height and weight must be measured before spirometry. Height is a predictor of lung function and it is very important that this is measured correctly by trained staff. No matter how simple the equipment, staff should be trained to record height and weight according to the guidelines in section below.

Height should be recorded to the nearest complete 1 cm using the same stadiometer for all measurements. It should be entered into results sheet (appendix 3) and the spirometer when prompted. The Harpenden wall mounted or pocket Stadiometer is recommended. Stadiometers attached to balance beam scales are not recommended.

1. Ask the participant to remove shoes, hat and bulky clothing such as coats and sweaters. You may need to ask some participants to adjust hairstyles or remove hair accessories that may interfere with measurement.

2. The participant should stand erect, with shoulders level, hands at sides, knees or thighs together and with weight evenly distributed on both feet. Feet should be flat on the floor (or foot piece) with both heels comfortably together and touching the base of the vertical board or wall. When possible, all four contact points (the head, back, buttocks, and heels) should touch the vertical surface while the participant also maintains a natural stance. Some people may not be able to keep a natural stance if all four contact points were touching the vertical surface. For these participants, at a minimum, two contact points — the head and buttocks, or the buttocks and heels — should always touch the vertical surface.

3. Ask the participant to move their head or position the participant's head by placing a hand on the chin and moving it into the Frankfort Plane. The Frankfort Plane is an imaginary line from the lower margin of the eye socket to the notch above the tragus of the ear. When aligned correctly, the Frankfort Plane is parallel to the horizontal headpiece and perpendicular to the vertical back piece of the stadiometer. This is best viewed and aligned when the investigator is directly to the side and at eye level with the participant.

4. Lower the horizontal headpiece until it firmly touches the crown of the head and is at a right angle with the measurement surface. Ask the subject to inhale deeply and check contact points to ensure that the lower body stays in the proper position and heels remain flat. Reposition the head board if necessary. Read the height to the nearest complete 1 cm. Always round down to the nearest complete 1cm. Do not round up. Record results immediately on questionnaire II and enter into the spirometer when prompted.

Weight should be measured to the nearest to 1 kg. Weight is not used as a predictor of lung function, but accuracy is still important and staff should be trained to use centres' weighing equipment correctly. The measurements should be recorded to the nearest 1kg or 1cm on Questionnaire and entered into the spirometer when prompted during lung function testing.

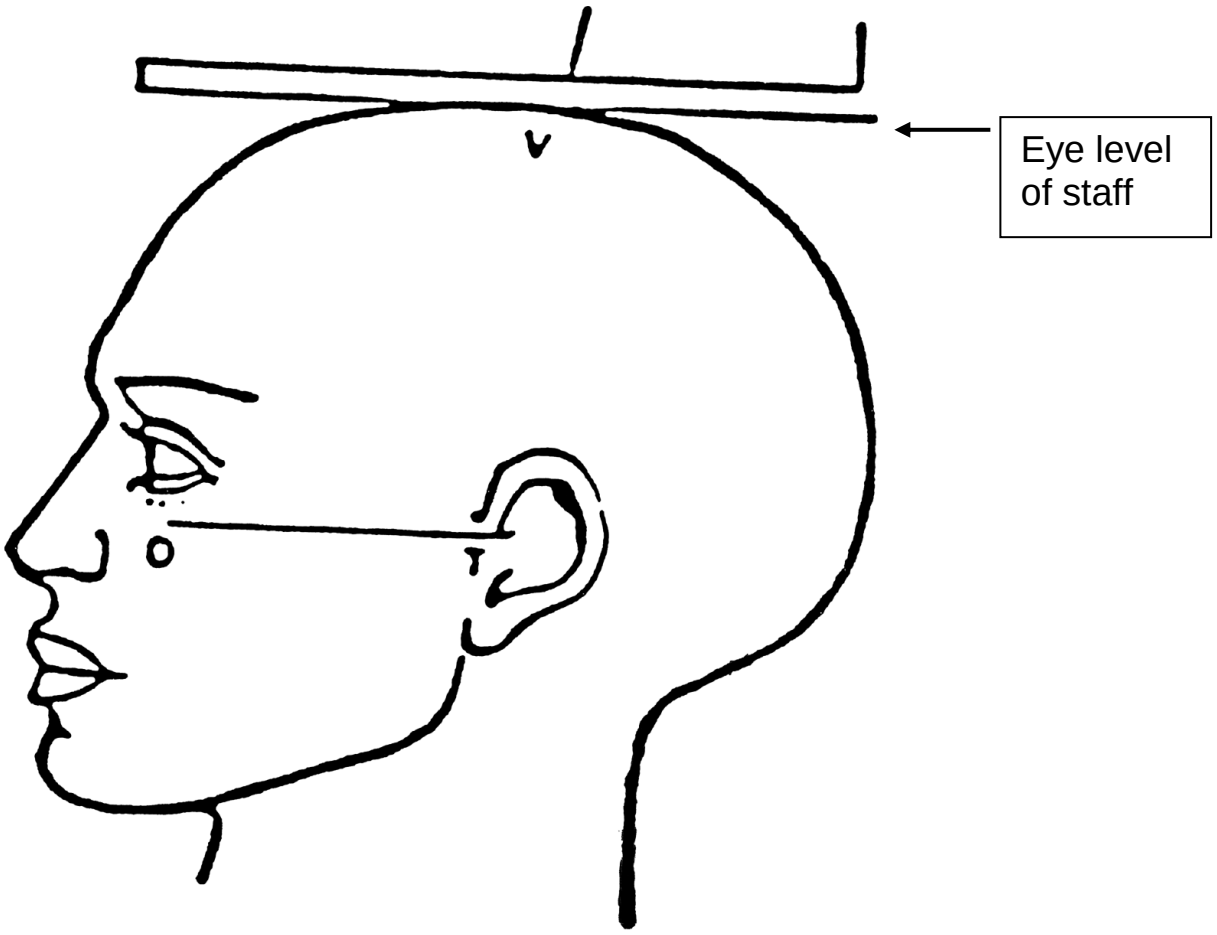
A digital scale or balance beam is recommended for the measurement of weight. The same scale should be used for all measurements. Ideally the scales should be calibrated at least annually by local procedure. In this study, monthly calibration is recommended.

Whatever kind of scale is to be used, checks should be made and any necessary adjustments to ensure that the scale reads '0' before each measurement.

The scales should be placed on a flat, firm floor surface. If weight has to be measured in carpeted areas, a small sheet of wood or hard plastic should be placed beneath the scale. The participant should ideally be wearing normal lightweight indoor clothing. Ask them to remove shoes, coats, jacket and heavy objects from pockets such as telephones or keys. Ask the participant to step onto the centre of the scale platform and stand up straight with arms relaxed at their sides and looking straight forward.

Staff involved in the recruitment should be properly trained to conduct height and weight measurements based on the on the method described here. Training should begin with a discussion and demonstration of the methods. The 'trainee' should then be asked to perform duplicate measurements on three different individuals. Height and weight should be recorded for each individual once and then the process repeated for a second recording of measurement. The 'trainer' should also undertake the same measurements on one occasion. Adequate training is achieved where the trainee's repeat measurements are within 1kg and 1cm of each other and the mean of the repeat measurements are within 1kg and 1cm of the trainer's measurements. If reproducibility is not met, repeat the training process -beginning with a review of the methods, until the required standards are achieved.

Figure 1 Frankfort Plane for measuring body height



Waist and hip circumferences (mm)

Equipment
Insertion tape calibrated in mm, with a metal buckle at one end

Procedure
Ask the participant to remove all outer layers of clothing,
e.g.; jackets, heavy or baggy jumpers, cardigans and waistcoats
Shoes with heels

Tight garments intended to alter the shape of the body e.g. corsets, lycra body suits and support tights
Belts should be removed or loosened for the measurement

Using the insertion tape
All measurements should be taken to the nearest millimetre. If the length lies half-way between two millimetres, then round to the nearest **EVEN** mm. For example, if the measurement is halfway between 68.3 and 68.4, round up to 68.4. And if the measurement is halfway between 68.8 and 68.9, round down to 68.8. Please note that you must enter the measurement to one decimal place - do not round it to the nearest centimetre. For example, enter '78.2', not just '78'. Ensure the respondent is standing erect in a relaxed manner and breathing normally. Weight should be evenly balanced on both feet and the feet should be about 25-30cm (1 foot) apart. The arms should be hanging loosely at their sides. If possible, kneel or sit on a chair to the side of the respondent. Pass the tape around the body of the respondent and insert the plain end of the tape through the metal ring at the other end of the tape. To check the tape is horizontal you have to position the tape on the right flank and peer round the participant's back from his/her left flank to check that it is level. This will be easier if you are kneeling or sitting on a chair to the side of the respondent. Hold the buckle flat against the body and flatten the end of the tape to read the measurement from the outer edge of the buckle. Do not pull the tape towards you, as this will lift away from the respondent's body, affecting the measurement.

Measuring waist circumference
1. The waist is defined as the point midway between the iliac crest and the costal margin (lower rib). To locate the levels of the costal margin and the iliac crest use the fingers of the right hand held straight and pointing in front of the participant to slide upward over the iliac crest. Men's waists tend to be above the top of their trousers whereas women's waists are often under the waistband of their trousers or skirts.

2. Do not try to avoid the effects of waistbands by measuring the circumference at a different position or by lifting or lowering clothing items. For example, if the respondent has a waistband at the correct level of the waist (midway between the lower rib margin and the iliac crest) measure the waist circumference around the waistband.

3. Ensure the tape is horizontal. Ask the participant to breathe out gently and to look straight ahead (to prevent the respondent from contracting their muscles or holding their breath). Take the measurement at the end of a normal expiration. Measure to the nearest millimetre and record this on the schedule.

4. Repeat this measurement again.

5. If you are of the opinion that clothing, posture or any other factor is significantly affecting the waist measurement, record this on the schedule.

Measuring hip circumference
1. The hip circumference is defined as being the widest circumference over the buttocks and below the iliac crest. To obtain an accurate measurement you should measure the circumference at several positions and record the widest circumference.

2. Check the tape is horizontal and the respondent is not contracting the gluteal muscles. Pull the tape, allowing it to maintain its position but not to cause indentation. Record the measurement on the schedule to the nearest EVEN millimetre, e.g. 95.4.

3. If clothing is significantly affecting the measurement, record this on the schedule.

4. Repeat this measurement again.

General points

The tape should be tight enough so that it doesn't slip but not tight enough to indent clothing. If clothing is baggy, it should be folded before the measure is taken.
If the respondent is large, ask him/her to pass the tape around rather than having to "hug" them. Remember though to check that the tape is correctly placed for the measurement being taken and that the tape is horizontal all the way around. If your second waist or hip measurement differs by 3cm or more from the first, the computer will give you a warning. If you have made a mistake when entering the figures (e.g. typed 78.2 instead of 68.2), you should type over the mistake. If it was not a mistake, you should suppress the warning and take a third measurement. If you have problems palpating the rib, ask the respondent to breathe in very deeply. Locate the rib and as the respondent breathes out, follow the rib as it moves down with your finger. If your respondent has a bow at the back of her skirt, this should be untied as it may add a substantial amount to the waist circumference. Female respondents wearing jeans may present a problem if the waistband of the jeans is on the waist at the back but dips down at the front. It is essential that the waist measurement is taken midway between the iliac crest and the lower rib and that the tape is horizontal. Therefore in this circumstance the waist measurement would be taken on the waist band at the back and off the waist band at the front. Only if the waistband is over the waist all the way around can the measurement be taken on the waistband. If there are belt loops, the tape should be threaded through these so they don't add to the measurement.

Recording problems

We only want to record problems that will affect the measurement by more than would be expected when measuring over light clothing. As a rough guide only record a problem if you feel it affected the measurements by more than 0.5cm. We particularly want to know if waist and hip are affected differently.

7.8 Smell Test

The Smell test, also known as “Sniffin’Sticks” is a test of the nasal chemosensory function measuring odour threshold, discrimination and identification of odour using a pen-like odour dispensing device.

The 12 pen Sniffin’ Sticks to be used in this study, is a **test for scent identification**. The test is a sensitive measure of smell and is important in conditions affecting the nasal chemosensory performance such as rhino-sinusitis. The test will be used to identify patients with olfactory dysfunction and as a validation of reported rhino-sinusitis symptoms.

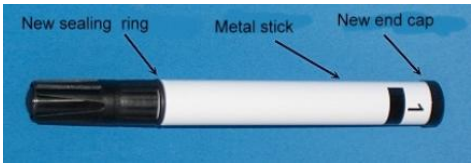
Materials for Smell Test performance

- Screening 12 tests kit produced by Burghart Germany
- Results sheet

Standard Sniffin’ Sticks kits FROM THE SAME PRODUCTION BATCH will be provided, or arranged to be provided by the co-ordinating centre to all participating centres!

The odor pens contain substances that were created by perfumers with the intention to imitate natural scents as best as possible and have the advantage of better reliability over natural aromas. The Sniffin' Sticks – Screening 12 is an identification test by design, meaning that different scents must be identified by the participant. It is a multiple choice test. The participant is offered 4 possible answers, from which one describes the scent in the best way. The participant has to do a 'forced choice' by giving one answer only. This technique minimizes responders' bias. The question to be asked is always "What does this smell like?"

The Shelf life of the Sniffin' Sticks is guaranteed for 12 months by the manufacturer



How to perform the Smell Test

- The test takes about 8 minutes.The test should be performed in a well ventilated room. There should be no disturbance during the test.
- Participant should be informed prior the visit that he/she should not eat or drink anything (but water),they should not smoke, chew gum, nor use any kind of drops 15 minutes prior the test.
- Information on what the test involves should be given. Participants should be told that this is a medical test and the smelling substances contained within the pens are not poisonous, nor harmful for allergic people in the given concentrations
- Remove the cap of the pen for presentation only
- For odour presentation, place the pen 2 cm in front of both nostrils. Ask the participant to sniff. Present the pen for 3-4 sec only. The longer the cap is removed, the more odour is released. This leads to adaptation of the patient to the odour, olfactory contamination of the environment, and decreased overall usability of the pen over time.
- Never touch the skin! A pen which accidentally touched the skin should be disposed and replaced
- Recap the pen as soon as the odour has been presented
- After presentation, place the pen in the kit box, **pointing down**. This will ensure a uniform emission of odorants
- Show the participant the multiple choice card with 4 possible answers for each pen and ask him/her to pick the answer that describes the odour best (see Appendix 17 for the smelling test to be used).
- Even if unsure or the participant cannot smell anything, the participant has to provide a best guess to each odour. Pictorial cards could be used for children. Mark the given answer in the response sheet.
- Allow an interval of 30 sec between pens. **This needs to be timed to ensure standardisation of duration**.
- Present all 12 pens, one by one, as described above, in the order they are numbered
- Information on results will be given only at the end of the test.

Record the results using the results sheet. This will be added to the clinical questionnaire, so results for each participant can be recorded and kept on the participant file.

ID	
Gender	
Age	

Mark the answer given by participant with a light coloured marker.

1	Orange	Blackberry	Strawberry	Pineapple
2	Smoke	Glue	Leather	Grass
3	Honey	Vanilla	Chocolate	Cinnamon
4	Chive	Peppermint	Fir	Onion
5	Coconut	Banana	Walnut	Cherry
6	Peach	Apple	Lemon	Grapefruit
7	Liquorice	Gum	Spearmint	Cookies
8	Cigarette	Coffee	Wine	Smoke
9	Cloves	Pepper	Cinnamon	Mustard
10	Pear	Plum	Peach	Pineapple
11	Camomille	Raspberry	Rose	Cherry
12	Bread	Fish	Cheese	Ham

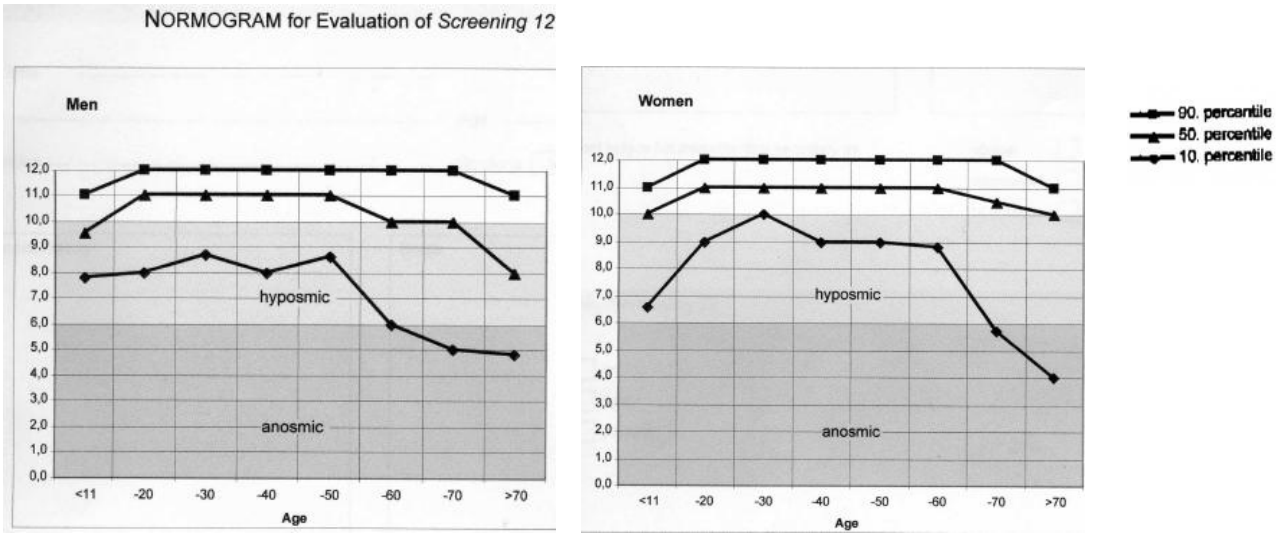
SCORE (sum the number of correct identifications) ☐

Please find the correct answers for scent identification on orange fields below.

1	Orange	Blackberry	Strawberry	Pineapple
2	Smoke	Glue	Leather	Grass
3	Honey	Vanilla	Chocolate	Cinnamon
4	Chive	Peppermint	Fir	Onion
5	Coconut	Banana	Walnut	Cherry
6	Peach	Apple	Lemon	Grapefruit
7	Liquorice	Gum	Spearmint	Cookies
8	Cigarette	Coffee	Wine	Smoke
9	Cloves	Pepper	Cinnamon	Mustard
10	Pear	Plum	Peach	Pineapple
11	Camomille	Raspberry	Rose	Cherry
12	Bread	Fish	Cheese	Ham

Results interpretation

By the end of the test, each participant has been presented all 12 scents and 'the scent identification' or the answers given were recorded. Then the answers are compared with the 'solutions' and the correct answers given by the participant are totaled. The result is a score that is compared to the age depending normative data of other participants. A normogram of scores could be drawn, showing the anosomic and hyposomic areas and on what percentile the participant falls (10%, 50%, 90% of the population). As there is a probability of 25% for each odor that the participant will give a good guess even if he/she has a seriously impaired smell, a score of '0' is therefore unlikely. A score 'zero' is rather an indicator the participant gives wrong answers on purpose.



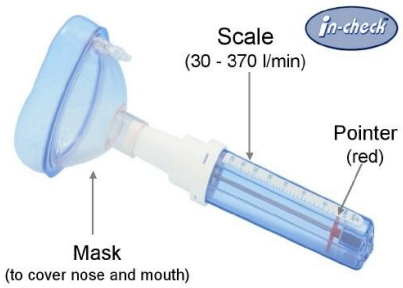
The olfactory performance increases with the age and decreases in elders. Plot the point for the score achieved by a participant and his age. The result will be interpreted depending on the percentile this falls in. For example, a 35 years old man who identified correctly 8 odors (score 8) falls under the 10 percentile line, meaning that 90% of men his age have a better sense of smell than him. If the score-age plot falls under the 50 percentile line, only 50% of the subjects having the same age as the participant have a better smell than the participant. If the plot falls under the 90 percentile line, only 10% of the subjects with the same age as the participant have a better smell than the participant. Results differ by gender.

7.9 Peak Nasal Inspiratory Flow (PNIF)

Peak nasal Inspiratory flow rate is a reliable and objective measure of airflow obstruction used for assessment of upper airways function which is impaired in conditions such as allergic rhinitis, nasal polyposis and structural nasal abnormalities. Simple to perform, cost-effective and non-invasive, we will be using PNIF as an objective marker for diagnosis of rhinitis including occupational rhinitis and validation of symptoms reported by study participants. Correlation of PNIF with patient's symptoms of blockage was shown to be sensitive. The test is reproducible and suitable for epidemiological studies. Both children and adults have shown good co-operation in performing the test.

7.9.1 Necessary Consumables for PNIF performance

- In-Check Inspiratory flow meter (see below)
- Mouthpiece connector (sterilisable)
- Facemask (see below)



The In-check device is a portable hand-held inspiratory flow meter produced by Clement Clark International. For nasal measurements, a standard In-Check Oral device is combined with a cushioned

face mask. The cushioned face mask is of a standard "anaesthetic" type, designed to enclose the nose and mouth completely, making an airtight seal.

The In-Check Nasal uses a simple measurement of how quickly the air can move through the nose when inhaling forcefully. The In-Check Nasal Inspiratory flow meter can measure inspiratory flow rates in the range 30 to 370 l/min, with an accuracy of +/- 10% or 10 l/min (whichever is the greater) and repeatability of +/- 5 l/min. The In-Check Nasal works when a patient inhales through the nose causing air to be drawn through the meter, a cursor moves along the scale to indicate the speed of inhalation. The flow rate achieved can be noted by checking the position of the cursor against the calibrated scale. The meter is manufactured from medical grade components, and is suitable for multiple patient use when cleaned appropriately between patients. The expected life of the In-Check, in normal use, is two years. It is essential that all centres use this make and model of PNIF meter. If you have difficulties sourcing this make and model please contact m.lim@imperial.ac.uk for assistance.

7.9.2 How to measure PNIF

Training will be provided. **Adequate instructions or demonstration should be given to participant before performance of the test!**

The steps in performing the test are as follows:

1. Assemble the In-Check device and the mouthpiece
Warning: To prevent choking, please make sure there are no foreign objects in the device before use!

2. Prepare the participant: explain the test, ideally make a demonstration! Remove spectacles of participant (if applicable) and **ask participant to blow their nose – gently!** Give instruction that the mouth should be closed all the time during the test and breathing performed only through nose. Underline that the participant should never blow into the device. **The meter can be compromised if participant accidentally blows into the device!**

3. Choose the appropriate mask for the participant performing the test. Different masks may be available in a variety of sizes to suit different facial shapes. Ensure that the mask forms an airtight seal against the face.

4. Attach cushioned face to the mouthpiece of the In-Check device

5. Ask the patient to fully exhale through the nose. The mouth should be closed, no breathing through.

6. Put the face mask on the face, hold the In-Check horizontally, and ensure the face mask forms and air tight seal around the nose (see picture below)

7. Instruct the participant to close their mouth and inhale forcefully **through their nose** (sniff). The peak nasal inspiratory manoeuvre should be a short, sharp inspiratory action of about one-second in duration.

8. Record the nasal inspiratory flow from the position of the red cursor against the scale.

9. Reset the In-Check by returning the red cursor to the start position. Be ready for the next test.

10. Repeat steps 4 to 9 to obtain **three readings. Record all three values in the patient's results sheet.**

7.9.3 Resetting the In-Check Nasal

1. Hold the instrument in a vertical position (with the mouthpiece uppermost) so that the rounded end of the meter can be tapped against the other hand (or a horizontal surface, such as a table but hand is preferable, will result in less damage to the In-Check!).

2. A firm tap will dislodge the magnetic resetting weight, which will return the red cursor to a start position. It is then important to invert the In-Check Nasal (turn through 180 degrees) to allow the weight to travel back to the magnetic holder.

3. DO NOT try to reset the In-Check Nasal as if it were a mercury thermometer- this action causes serious damage to the piston and pointer.

Resetting the In-Check Nasal - Stages One to Five

7.9.4 How to disinfect the In-Check

The mask should be disinfected between participants to avoid the risk of cross infection or single use masks should be used for each participant.

1. Disassemble the In-Check Nasal into the three component parts - Facemask, Mouthpiece and In-Check meter.

2. Immerse the In-Check Nasal in warm (but not hot) mild detergent solution for 2-3 minutes (maximum 5 minutes). The compatible solutions for CCI devices are: Lancerzyme, Cydezime, Hospek. Prepare the solution as per manufacturer indications, in a large enough container for the meter to be totally submerged into the solution. Agitate the meter to ensure thorough cleaning.

3. Rinse in clean warm water and shake gently to remove any excess water. It is important to rinse thoroughly to prevent salt spots appearing on the body and spindle.

4. Allow to dry thoroughly before using again. (You may need 10 or more devices/kits per centre, depending on how many participants you intend to see each day.)

Note: The Facemask and mouthpiece can be cleaned in a similar way.

The frequency of disinfection needs to be estimated according to the local Nosocomial Infection Control rules. Sterilizable plastic mouthpiece need to be sterilised after each participant. This therefore means

that each participant is presented with a sterilized kit. At the end of each day the PNIF kits can be sterilised and left to dry over night for re-use the following day.

Damage has been caused to In-Check meters through the use of excessive force when trying to shake water from the meter after cleaning. Please ensure that the meter is shaken by holding the ROUND END only - to hold the other end and shake the meter can result in the resetting weight damaging the piston & spring assembly.

How to shake water out of In-Check Nasal

How NOT to shake In-Check

DAMAGE TO THE IN-CHECK CAN RESULT!!!

Occasionally, the resetting weight is not easily dislodged. In such cases, bang the rounded end of the meter against a hard surface (such as a table-top, although not if it is made of glass).

7.9.5 Normal values range for statistical analysis.

Inter - and intra-patient variation, day variation (measurement should be performed daily at the same time, and this time should be recorded) make the interpretation of the test results a bit difficult. Repeated measurements on one occasion in trained subjects show a coefficient of variation of about 6%. Nasal airway patency varies with time and in many normal individuals the PNIF may vary in the course of the day by more than two-fold. Post decongestant readings are much more consistent, and consistency is also improved by avoiding factors associated with changes in the nasal airway, such as extremes in temperature or humidity, spicy foods or irritant fumes etc.

Performance accuracy
Accuracy +/- 10% or 10L/min (whichever is greater) and repeatability of +/- 5L/min.

7.10 Lung function with reversibility

Trained staff should carry out each spirometry session according to the SOP described in the Section below. During a spirometry manoeuvre there is a small risk that the participant may faint and hurt him/herself while falling. **Participants must therefore perform the manoeuvres in the seated position, in a chair with arms but without wheels.**

7.10.1 Overview

Spirometry is one of the simplest, most effective tests available for the assessment of lung function. A spirometer measures the amount of air a subject inhales or exhales and the rate at which the air is exhaled. The most common spirometric tests require the subject to exhale with as much force as possible after taking a full, deep breath. This is called the forced expiratory manoeuvre.

This study aims for all centres to undertake uniform measures of lung function. The same type of spirometer will be used across all centres - the ndd EasyOne Spirometer. This is a highly portable spirometer that measures flow and volume by ultra-sound transit time. It is endorsed by the ERS and complies with ATS spirometry standards.

Every spirometry session must be performed according to the SOP by study staff or technicians trained to do so. To ensure data integrity equipment must be regularly cleaned and the calibration checked daily according to manufacturer instructions. **Always check that the EasyOne configuration settings are set to the study parameters and install the Easy Ware software in the English language version. (Appendix 16)**

During the course of data collection spirometric manoeuvres will be continuously reviewed by the co-ordinating centre to provide feedback to study investigators for every 30 spirometries performed and ensure maximum quality.

7.10.2 Measures

During each session the following measures should be collected:

Forced Vital Capacity (FVC)	The total volume of air exhaled in a forced expiratory manoeuvre. The FVC is useful for detecting restrictive diseases, since lower than expected results may be a sign that the lungs cannot inflate normally. FVC is reduced in people with obstructive and restrictive disorders.
Forced Expiratory Volume at One Second (FEV_1)	The amount of air that a person exhales during the first second of a forced expiratory manoeuvre and is reduced in individuals with airflow obstruction.
The ratio of FEV_1 to the FVC (FEV_1/FVC)	The most sensitive and specific index of airways obstruction measured by a spirometer. It is obtained by dividing the FEV_1 by the FVC, and is expressed as a percentage (100 x FEV_1/FVC).
Forced Expiratory Volume at Six Seconds (FEV_6)	The amount of air that a person exhales during the first six seconds of a forced expiratory manoeuvre. Increasing interest is being shown in the FEV_6, and more particularly in the FEV_1/FEV_6 ratio, as an alternative to the FEV_1/FVC ratio.
The ratio of FEV_1 to the FEV_6 (FEV_1/FEV_6)	An alternative to the FEV_1/FVC ratio.

These volumes are measured **before and after bronchodilator administration.**

7.10.3 Location

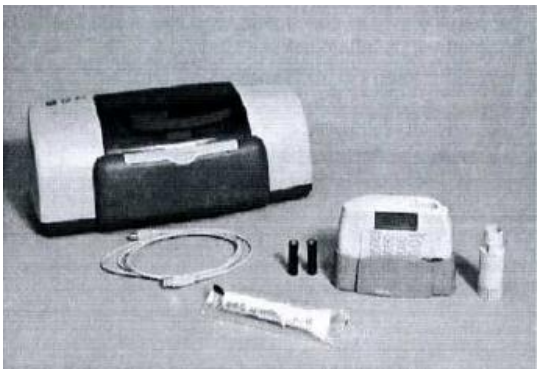
Spirometry testing ideally should be performed in a private, temperature-controlled room. All necessary equipment should be available in the room. Ideally the room should be well lit, preferably with a window, and located in a quiet area of a clinic. These conditions will improve the quality and reproducibility of the results. For safety, the participant must be seated in a chair with arms but without wheels.

Some centres may need to carry out the clinical visits in the participant's home. The ndd EasyOne Spirometer is portable and has been shown to perform well in the field. Nonetheless, this SOP assumes that testing will be done at a central clinic. Centres that do otherwise are advised to develop corresponding local procedures and document them in their local Manual of Procedures.

7.10.4 Equipment

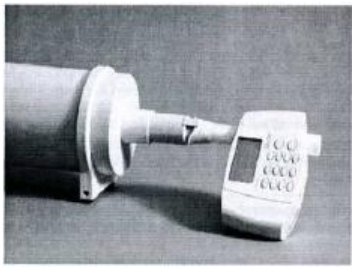
The spirometry session should be carried out in a room with the following equipment:

Sink for hand washing, soap and hand towels
Containers of:
clean mouthpieces (Spirettes)
nose-clips
Containers to collect:
used Spirettes
used nose clips
Box of tissues
Alcohol wipes
Disposal bin
Clinical gloves
Chair with arms/without wheels
Spare AA batteries
EasyOne Spirometer
Calibration syringe & syringe adapter
Bronchodilator (Ventolin)
Drinking water and cups/glasses



7.10.5 Calibration

The EasyOne Spirometer has been designed to need no calibration. The instrument can however develop faults and we request that a calibration check be carried out daily during the course of the data collection. Instructions for performing the calibration check is in the ndd EasyGuide technical manual (page 23). The calibration syringe and adapter should always be stored next to the spirometer so that the temperature between them is similar. If spirometry is done in the field (outside a clinical setting), it is preferable to keep the spirometer and calibration syringe together overnight to avoid temperature differences at the time of calibration. Contact the co-ordinating centre **immediately** if the EasyOne develops a fault.



7.10.6 Medication use prior to testing

In order to provide a valid lung function assessment, participants should be asked to refrain from taking bronchodilators during the 6 to 12 hours before their clinical visit appointment. The exact omission time depends on the type of medication.

Type of medication	Avoid for:
short-acting beta-2 agonist	4 hours prior to the visit
anticholinergic inhaler	6 hours prior to the visit
oral beta-2 agonist	12 hours prior to the visit
oral theophylline	12 hours prior to the visit
oral antimuscarinic	12 hours prior to the visit
long-acting beta-2 agonist (Serevent)	12 hours prior to the visit

If the participant has not been able to comply with these waiting periods, the spirometry can be done anyway, but this should be recorded. It is preferable that the participant make another appointment if they are willing.

7.10.7 Reasons for rescheduling spirometry testing

In some instances, spirometry testing may be contraindicated by a temporary condition that would affect the validity of the manoeuvre or endanger the health of the participant. These situations are at the discretion of the investigator/ spirometry technician – examples may include: acute back pain; a respiratory tract infection with unresolved symptoms in the week prior to the visit; or recent dental work.

Ideally, centres should postpone testing and should re-schedule the visit for a time when the situation could be expected to be resolved. If participants are brought back later for spirometry testing, but the rest of their data are collected on the first visit, then the Spirometry safety questions must be asked again and the date of spirometry entered onto Questionnaire.

7.10.8 Contraindications for testing

Testing should **not** be done if the subject has or reports any of the following:

- a heart attack in the last three months
- chest or abdominal surgery in the past 3 months
- a detached retina or eye surgery in the past 1 month
- if they are a woman in the last trimester of pregnancy
- they are taking medication for tuberculosis
- any other co-morbidity (such as unstable angina or pneumonia) that, in the opinion of a local clinician, may affect the performance of the test or impact the participant's safety

If a participant has or reports any of the conditions above do not proceed with spirometry. If they agree, participants may be brought back for retesting at a later date.

7.10.9 Method

A detailed description of the use and operation of the ndd EasyOne spirometer, together with instructions for coaching the participant, are included in the ndd EasyGuide users' manual. All study staff who undertake the lung function tests are asked to read this document and to be familiar with its contents and that of this SOP. A copy of this document should be kept with each spirometer in case questions arise during testing.

Always check that the EasyOne configuration settings are set to the study parameters.

These will be set during the training workshop – also see appendix 16 for a check list of these parameters. Centres that already have spirometers from SARI should use them and the existing settings as for SARI. Ideally, a central person responsible for configuration of the EasyOne^{TM} will be designated at each clinical site.

Participant information should be entered into the spirometer as prompted. In the ID field enter all 5 digits of the subject's unique ID.

As prompted enter the age, height, weight, ethnic category, gender, smoking status and allocated project staff ID of the person undertaking the test (Always input your same allocated 'Staff ID' -this is your two digit or two figure personal ID or initials, always use the same ID)

If after safety questions it is decided to reschedule the session, ensure that the same questionnaire is recalled for use at the second visit. If testing is to proceed offer participants the opportunity to use toilet facilities before testing. Instruct them to loosen any tight clothing that might restrict inspiration. Testing should be conducted with the participant seated, upright and with chin slightly elevated on a chair with arms but no wheels. The chair is a safety measure to support the participant in case s/he faints during the manoeuvre.

Staff and participants should wash their hands before the start of the test and use a tissue or gloves to remove mouthpieces (the Spirette) from its packaging. Allow the participant to insert the clean Spirette into the spirometer. Be careful to ensure that the arrow on the Spirette is lined up with the arrow on the spirometer.

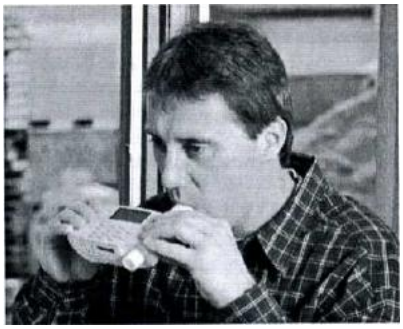
All manoeuvres should be performed with the participant wearing a nose clip. This clip prevents air from moving through the nose during the test.

A good rapport with the participant will improve the quality of the test. Explain that the purpose of the test is to take some measurements to check on the health of the lungs. Emphasize that, although the procedure does not hurt, in order to get useful and valid results he/she must breathe out as hard and as fast and for as long as is possible when told to do so, and will need to repeat the procedure a few times.

7.10.10 Pre-bronchodilator test

After instructing the participant about the procedure for pulmonary function testing and asking all the safety questions, proceed with the actual testing, following the procedures outlined in sections 5.2 to 5.4 of the ndd EasyGuide^{TM} users' manual. This initial series of manoeuvres is performed **BEFORE** administering the bronchodilator.

Explain that the participant should take in as deep a breath as possible, and when his/her lungs are totally full, quickly position the mouthpiece and BLAST out the air as hard and as fast as possible. A vigorous demonstration of the manoeuvre will help the participant understand the manoeuvre much more quickly. Demonstrate the correct positioning of the mouthpiece. Take a deep breath and emphasize the full depth of inhalation. Then demonstrate a dramatic blast out as fast as possible. Because the adequacy of these manoeuvres is highly dependent on participant effort, staff must guide the participant through the technique. It is extremely important to inhale as fully as possible and to exhale very forcefully, and as much as possible. Tell the participant when to start taking in a deep breath and to put the mouthpiece in his/her mouth. Then tell them to blast out the air and to continue exhaling for at least 6 seconds. Observe their body language as he/she attempts to follow the instructions, and encourage them to continue blowing out smoothly **without re-breathing.** Instruct the participant to remain erect and not to bend over during the manoeuvre.



Follow the procedures outlined in sections 5.2 to 5.4 of the ndd EasyGuide users' manual. Follow the computer prompts until a successful test session has been obtained. A successful test session is defined as at least three acceptable manoeuvres, with both the two best FEV_1s and the two best FVCs from these manoeuvres within 200 ml of each other.

7.10.11 Administer the bronchodilator

After at least 3 acceptable and 2 reproducible manoeuvres (see below for definitions of "acceptable" and "reproducible") are obtained, administer **two puffs** of bronchodilator (short-acting beta-agonist, Salbutamol, 100 mcg per puff) to the participant using a standard spacer e.g. Clement Clarke Able Spacer . These need to be available at each centre. A new unit should be used for each individual unless appropriate sterilisation procedures are approved by your centre, and used units should be disposed of in the appropriate manner. See the MDI checklist (appendix 13) for the steps in bronchodilator administration.

For optimal distribution of the bronchodilator, these steps should be followed carefully. A timer should be set up to sound 15 minutes after the last administered puff. During the waiting time, the technician should administer the study questionnaires. The effect of the bronchodilator will persist, and actually slightly increase, for at least the next 30-40 minutes. Technicians may therefore choose to complete the questionnaires between the pre- and post-BD manoeuvres.

Note of caution: Beta2 Agonists should be used with caution in people who suffers from hyperthyroidism, cardiovascular disease, arrhythmias, susceptibility to QT interval prolongation and hypertension.

7.10.12 Maximum Post-bronchodilator manoeuvre

The post-bronchodilator (BD) manoeuvre can start anytime **after the 15-minute wait.** The same criteria of at least 3 acceptable and 2 reproducible manoeuvres should be followed. It is not critical that the post-BD manoeuvre be done immediately at 15 minutes, but rather that it is done at least 15 minutes after the last administered puff of bronchodilator.

7.10.13 Acceptable and reproducible manoeuvres

"Acceptable" is defined as a manoeuvre that is free from error. "Reproducible" is defined as being without excessive variability between manoeuvres. Three acceptable manoeuvres are needed to be 'reproducible'. The two highest values for FVC and FEV_1 taken from acceptable forced expiratory manoeuvres should not vary more than 200 millilitres from the second highest FVC and FEV_1. It is also important to monitor the volume-time curves to determine if the size and shape of the curves are reproducible.

Many factors will result in error, including hesitation or false starts, cough, variable effort, glottis closure, early termination and leaks. When errors do occur, review them with the participant before proceeding

with additional manoeuvres. You may wish to repeat a demonstration manoeuvre. Demonstrate the correct placement of the mouthpiece, emphasize the maximum depth of inhalation, and then blast out the air. If the participant tries again and the reproducibility criteria are not met, continue the test as needed (up to a total of 8 manoeuvres), assuming that the participant is able to continue.

When errors occur, review common errors with the participant before proceeding with additional manoeuvres.

Ask the participant to watch the technician perform the FVC manoeuvre again. The technician should demonstrate the correct placement of the mouthpiece, emphasize the maximum depth of inhalation, and then blast out the air. If the participant tries again and the reproducibility criteria are not met, the technician should continue administering the test as needed (up to a total of five manoeuvres), assuming that the subject is able to continue.

Some participants may never be able to provide three reproducible manoeuvres. The goal of each session is to meet the acceptability and reproducibility criteria, but these are not absolute requirements for data to be used. Previous studies have shown that inability to perform reproducible spirometry, even with good coaching, is an important risk factor in predicting future health. See Section 12 – Quality Control, for discussion on how to increase the quality of manoeuvres.

7.10.14 Spirometer calibration, maintenance and hygiene

The EasyOne spirometer is designed to reduce the need for cleaning and maintenance (see sections 13 and 14 in the EasyGuide users' manual). The surface of the spirometer and cradle may be cleaned by wiping with a damp cloth. If a more thorough cleaning is desired, the spirometer and its spirette cavity may be cleaned with an alcohol wipe or a soft cloth that has been lightly moistened with isopropyl alcohol. **Do not let liquids flow into the Spirette cavity of the spirometer while cleaning.** The disposable Spirette eliminates the need for cleaning the spirometer between patients. The Spirettes are designed for single patient use only, and must be removed and disposed of after each participant. Nose clips should be thoroughly cleaned after each use with hot water and detergent, allowed to dry and then wiped with alcohol.

It is recommended that staff and, if possible the participants, wash their hands before and after testing and that proper attention be given to environmental controls in settings where tuberculosis or other diseases spread by droplet nuclei are likely to occur. Participants with evidence of obvious upper respiratory infections should not be tested, but rather asked if they may be tested at a later date.

Beyond battery replacement and the calibration check, the spirometer requires no maintenance. No service should be performed on the spirometer except by manufacturer-authorised personnel.

7.10.15 Data transfer

Centres will be required to have ndd EasyWare PC-software which is compatible with a PC running Microsoft Windows 98/ME/2000/XP. EasyWare software is available in a number of languages, however centres are asked to **install the software in the English language version**. This is important. All databases will be regularly merged with the master database at the co-ordinating centre.

Ideally data should be transferred to a local PC daily. They should then be transferred to the Follow Up Project Website (see section 11.) Centres will receive feedback on quality control throughout the spirometry data collection.

7.11 Allergy skin sensitivity test

Skin sensitivity tests are practical in epidemiological surveys and are generally acceptable to the public. They give a semi-quantitative measure of sensitisation and are relatively cheap.

Skin prick testing will be carried out using skin testing reagents and standard lancets available commercially will be centrally and distributed to centres. Arrangements for soluprick solutions from the same production batch to be used by partners will be made by the co-ordinating centre, so each centre can have standardised tests.

A standard list of allergens will be used in all centres. Because there are cross-reactions between allergens, and sensitivity to regional allergens may be found outside the region of that allergen's usual distribution, the list includes some allergens which are regionally restricted. Each subject will be skin tested using the following panel of allergens:

1. Timothy Glass
2. Grass Mix
3. Der pteronyssinus
4. Cat
5. Birch
6. Blattella
7. Olive
8. Alternaria
9. Dog
10. Artemisia
11. Parietaria
12. Der farinae
13. Histamine (Positive Control)
14. Dilutant (Histamine Control)

7.11.1 Equipment

Skin test solutions must be stored at +4^{o}C when not in use. If the reagents are to be used >½hr from a refrigeration point then they should be kept in a cool box during transport to and from their usual storage location.

Other necessary equipment:

- skin test grid for application of tests (Appendix 4)
- lancets
- tissues
- sink, soap, hand towels
- clinical gloves
- sharps bin
- transparent scotch 3M tape at least 25 mm wide
- ball-point pen or fine felt tip pen
- timer with alarm.
- antihistamine cream
- Skin prick test results sheet

7.11.2 Method

First ask question spt1. (See appendix 3: Results sheet). If the participant has taken systemic antihistamine that may have an effect on the test, tick the yes box, but continue the test nonetheless.

A template for the skin test grid is provided in appendix 4. This can be printed onto transparent paper (such as overhead projection paper) and then the grids cut out as required. The same grid can be used

for several different participants, so long as they are cleaned with water and detergent and then wiped with alcohol between uses. Trained study staff should carry out the skin testing according to the following instructions:

Wash hands and apply clinical gloves

1. Place a clean test grid on volar surface of the forearm and fix with transparent or surgical tape. Mark the orientation of the grid on the subject's arm (e.g. mark top and bottom of grid).

2. Place a small drop of skin testing solution in the centre of each grid square. (Apply the skin test allergens in the same order during each test.)

3. Unwrap a lancet according to manufacturer's instructions. Hold the lancet at 90^{o} to the skin and with the forefinger press through the drop against the skin for at least 1 second. Very little pressure is required. A small impression may be briefly visible on the skin. The skin should not be broken to the extent that blood is drawn. Always apply the same pressure.

4. Remove the lancet with an upward motion and discard into a sharps container.

5. Change the lancet skin puncture device between each allergen test sites to avoid false positive results.

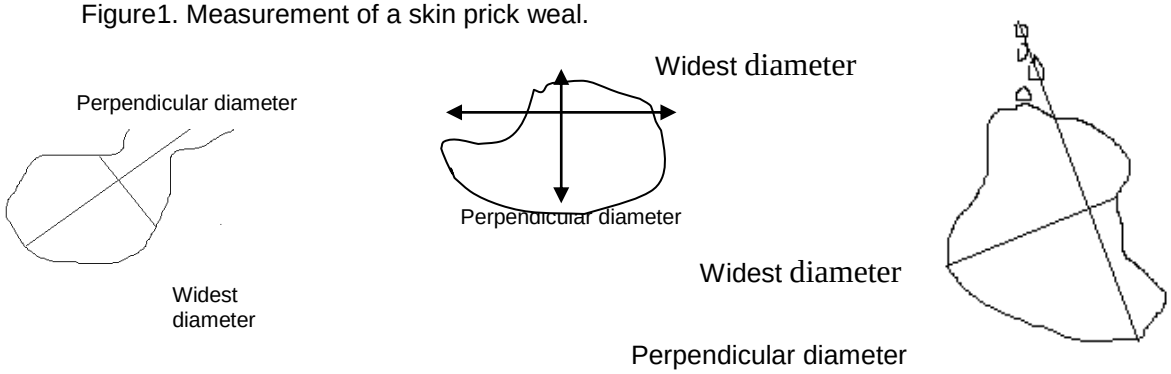
6. Remove the skin test grid. Blot any excess solution with tissues taking care not to cross-contaminate the tests.

7. Set the timer alarm and read the results after 15 minutes. During this wait, review the self administered questionnaires.
8. To record the results of the skin prick test draw around the perimeter of each of the wheals with a ballpoint pen or fine felt-tip pen. Always draw in the same order as the application of the tests.

9. Press a strip of transparent Scotch tape against the skin and transfer the prints to the grid on the results sheet. The transfer should always be placed at the same orientation marked on the grid.

10.From the transfer first measure the weal diameter (mm) at it's widest. The second diameter is called the 'perpendicular diameter'. This should be drawn at 90^{o} to the first diameter and **at the mid-point** of the first diameter. The second diameter may therefore not necessarily be at a wide point on the weal. Record both diameters to the nearest whole millimetre on the results sheet.

Figure1. Measurement of a skin prick weal.



11. When rounding to the nearest whole millimetre use the convention: 1.0-1.4 mm round down (1 mm), 1.5- 1.9 mm round up (2 mm).

12. If the participant has itchy and uncomfortable wheals after testing, reassure them that they will normally resolve after ½ hour and apply antihistamine cream as required.

Training
Project study staff must be trained to perform skin tests consistently and in a standardised manner. Before starting the study, staff should perform two histamine skin tests on each of 10 participants (total 20 tests done by each trainee). The results can be recorded on the allergy skin test training sheet supplied in Appendix 14. Participants can be tested with allergens if they wish, but only the histamine weal results need be recorded for the purpose of the training.

Trained staff should have a coefficient of variation (CV) of less than 30%.
The coefficient of variation of each staff member is carried out as follows:

Calculate the log to base e of each mean weal diameter recorded in mm.
If there are exactly two skin tests carried out on each participant:
Use the following formula to calculate the CV:

$$CV = \sqrt{\frac{\Sigma(d^2/2}{n}} \times 100$$

where
d = difference between two $\log_e$ values for each participant
n = number of participants

Use the coefficient of variation calculation sheet provided in Appendix 14

If there are not exactly two skin tests for each participant:
A between participant one-way analysis of variance can be carried out using a suitable computer program or calculator. Obtain the residual mean square, take the square root and multiply by 100 to obtain the CV (%).

Trainees should also administer the entire panel of allergens on five occasions and record them on a skin prick test result sheet (as per Method sub-chapter) before starting data collection with study participants. Document that this training has taken place.

7.12 Blood sampling

Approximately 20ml of blood should be taken from participants.

At least 6ml of blood will be taken using EDTA tubes for DNA extraction later. **Appropriate ethical and legal approval must be obtained to cover: a) taking of the blood b) storage of the whole blood c) transport of whole blood (or extracted DNA)** to a central laboratory that may be in another country. In most countries this will require frequent review by ethics committees.

The rest of the blood sample will be collected in serum separator tubes for later processing to produce serum samples. The serum collected will be stored locally prior to transport to a central laboratory (in Amsterdam) for measurement of IgE and sex hormones. Residual serum may be used for other purposes at a later date and permission from participants and ethical committees should recognise that a 'serum bank' will formed for future research (only for asthma, allergy and allergic disorders).

Note: **Further ethical approval will be required from Research Ethics Committees when the precise nature of this future research is agreed.**

It is vital that all centres collect high quality samples with standardised labelling to allow for central analysis. It is probably the single most important aspect of the data collection that participant's stored samples are labelled with the correct bar code sticker. Staff should be trained and insured to carry out Venepuncture according to local requirements.

7.12.1 Equipment

Clinical gloves
Sharps bin
Tourniquet
Cotton Wool swabs
Plastic storage tubes 6 X 2ml
Small receiver
Spot plasters/micropore
Blood spillage kit
Barcode stickers
Checklist for order of draw
Washable pillow
Suitable couch or chair (with arms and without wheels).

Cool box and tube rack (if the field)
BD Vacutainer™ Plastic Blood Collection Tubes, - 2 x 7ml gold top serum separator, 1x 6ml lavender top EDTA

7.12.2 Method

Explain the procedure to the participant and ascertain if they may feel faint when giving a blood sample. If so, ask them to lie down. Otherwise they should be positioned comfortably with their arm straight and resting on a hard surface or pillow.

Wash your hands and apply gloves.

Using a tourniquet, locate a suitable vein for venepuncture (median cubital, basilic or cephalic)

Insert vacutainer needle into holder.

Insert needle into vein, insert first bottle into vacutainer holder, pushing it firmly into place and ensuring it pierces rubber stopper allowing the vacuum to be completely filled.

Remove bottle from holder, keeping needle situated in the vein and continue to fill the blood bottles in correct order of draw. **Mix each blood tube as required before inserting a new tube.** The exchange of vacutainers should be smooth and the final blood tube removed prior to the needle being withdrawn from the vein.

When draw is complete, remove the tourniquet and gently withdraw the needle from the vein and place cotton wool swab firmly over the puncture site. Apply pressure to the puncture site for approximately half-a-minute.

Dispose of sharps directly into a sharps bin and transfer other contaminants to a clinical waste bag. Ensure that the outside of the blood bottles are free from blood. Label the EDTA tube with one of the subject's ID bar-coded stickers. Ensure that the sticker is aligned lengthways and at the top of the blood tube, that is with the longer end of the sticker placed lengthways along the tube so that the entire barcode and ID number are visible, flat and not obscured by any overlap.

It is not necessary to barcode label the serum collection tubes as they will be disposed of after centrifugation (carefully write the ID code onto the serum bottles). The stickers are made with expensive durable materials and only 14 labels per subject will be provided

7.12.3 Preparing a high quality sample

Equipments
A fridge
A -20ºC freezer
Freezer thermometer
Swing head or fixed angle centrifuge
2ml (Sarstedt) storage tubes – (or tubes suitable for -20ºC freezing and that can fit 24x13mm labels) and lids
Sarstedt tube storage boxes
Laboratory safety equipment (lab coat, glasses, gloves)
Disposable graduated 3ml pipettes
Barcode stickers
Barcode reader
Laboratory sample logbook
Results sheet

It is important to maintain an **impeccable sample logbook**. Copies of it will be required during sample shipment. An example of a logbook page is given in appendix 15. The page can be photocopied and a bound file of log pages prepared for use in the project. Keep an electronic list of the stored sample ID numbers, the number of each aliquot, and the date of draw. Transfer this file to the web pages before sample shipping.

An at least weekly record of the freezer temperature should be noted in the logbook.

All study project centers are asked **to use the same** BD Vacutainer Plastic Blood Collection Tubes where possible. These contain either anticoagulant or clot activator and therefore require immediate mixing following collection. The tubes with anticoagulants need to be mixed to ensure the specimen does not clot and tubes such as the BD SST™ with activator need to be mixed to ensure complete clotting.

During blood collection allow the vacuum in the tube to be completely exhausted.
Immediately after drawing, hold tube upright and gently invert 180º and back.
Repeat movement as prescribed for each tube and in the correct order of draw as detailed below:

Tube	**Collects**	**Tube colour**	**Number of inversions**
BD SST™ Gel Separator Tube **3x 5ml tubes (367954 or 367955)**	Serum	Gold	5
EDTA **1x 6ml tube**	Whole blood	Lavender	8-10
Storage Tubes **4-6 x 2 ml tubes**	Storage of serum	Transparent	0

The samples should be treated as follows:

Serum

The two serum collection tubes should be collected first. One will be used for IgE and sex hormone analyses, one for serum bank storage.

- Collect 2 tubes of up to 7 ml of blood in each BD Vacutainer (2 x 7ml gold top serum separator). Invert the tubes 5 times immediately after draw to ensure mixing with the clot activator. Label the tubes with the participants ID number and "today's" date onto the label on the tube **(these tubes will be centrifuged and then the serum drawn into aliquots so there is no need to place a barcode sticker on these tubes).**

- **let the blood clot for 60 minutes**
- spin the tube in a centrifuge at 3000 rpm for 15 mins to separate serum. **Gel separation tubes should ideally be centrifuged no later than 2 hours after collection**. A gel barrier will form separating the serum specimen from the clot.
- pipette the serum and transfer it into storage microtubes with rubber seal cap (2 ml each) SARSTEDT

- All tubes will be shipped to Amsterdam for analyses and serum banking / DNA banking.

The sample storage tubes must be labeled with the correct ID barcode label. Stick the label lengthways on the tube. Do not wrap the label around the tube (ensure that the whole of the bar code and ID are visible). Use a laboratory pen to write the sample type (serum) on the sticker. It should have ink that will not run during freezing and thawing. **Do not write over the ID number or bar code**. If there is little space write 'S' for serum clearly on the label. Store the sample tubes in a carefully labeled storage box at -20ºC. This activity must be entered into the study sample logbook, which will record the date of sample draw and storage along with an ID bar code sticker for each set of samples stored and a record of the number of 2ml aliquots of each sample type.

Samples ***may*** be stored in a fridge overnight before they are centrifuged. This should only be the case if for example. It is late in the evening and the technician needs to go home, then the samples can be store in a fridge overnight, and spun **first thing** the following morning, adhering to the instructions above.

Fit the tubes in small boxes/racks (never in plastic bags!) (see picture below), place them in a thermo-box, with cold packs. Dry Ice is not necessary for serum transfer. Use a shipment company which can deliver the samples within 2 days (i.e.Fed-Ex)

The samples for IgE will be analysed under supervision of Dr Ronald van Ree at:

AMC, Department of Experimental Immunology
attn: R.van Ree, L. Zuidmeer
Room K0-130 / room K0-134
Meibergdreef 9
1105 AZ Amsterdam
The Netherlands
Tel: +31-20-5666076, Resp.+31-20-5666819/806
Email: R.vanRee@amc.uva.nl or l.zuidmeer@amc.uva.nl

Note: Study centres are required to inform R. van Ree or L. Zuidmeer via telephone or fax before despatching the samples to Amsterdam.

Whole blood

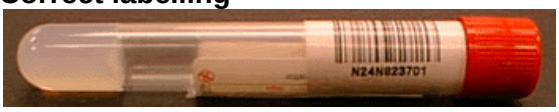
The EDTA blood bottle should be filled last. About 5 ml sample should be obtained from both adults and children.

It should be inverted 10 times to ensure complete mixing with the anticoagulant. The EDTA tube should be correctly labelled with the participant's ID and bar code sticker. The sticker must be placed lengthways and towards the top of the tube so that both the ID number and bar code are fully visible. Transfer the tube immediately into freezer. Freeze all tubes on the same day at **-20^{0}C.** Tubes should never be thawed until sent to lab for analysis. Collect all tubes in the same freezer. This activity must also be entered into the study sample logbook.

7.12.4 Labelling

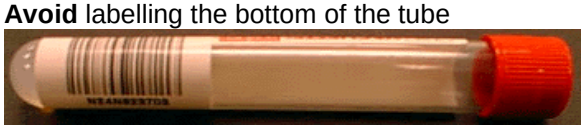
The co-ordinating centre will provide each participating centre with the necessary bar-coded labels, suitable for long term freezing. Tubes need to be correctly labelled, in order to allow automatic reading and registration of samples received by the lab. Place label starting at the top of the tube. Place the sticker lengthways on the tube. **It is vital that these labelling instructions are followed accurately. We do not get a second chance to label tubes. The labels will not stick to frozen tubes.**

Correct labelling

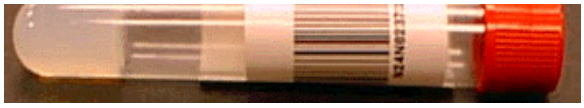


Incorrect methods

Avoid labelling the bottom of the tube



Do **not** wrap labels around the tube



Avoid wrinkles, folds or tears in label

Avoid incomplete or illegible labels

7.12.5 Shipment of bloods

Use a reliable courier, with package tracing and who complies with transport rules of the EU. Ask in advance if delivery can be guaranteed within 2 days. We recommend FEDEX

http://www.fedex.com/us/pckgenvlp/ship/

Each centre has to make their own arrangement for shipments and inform the co-ordinating centre this has been done. A copy of the log book should be shipped with the samples and another electronic copy of the log book of the samples transferred should be forwarded to the co-ordinating centre. **The original log book must to be kept at the centres**.

Pack your samples in plastic storage boxes and seal them. Put these boxes on 5-10 kg dry ice in a polystyrene box. Seal the box with an adhesive tape (sealing may give an extra 24 hour standby reserve). It is important to keep all samples frozen until the laboratory receives them.

Label the parcel with "**pathogen free, non commercial blood samples for research use only**".

Please inform the contact persons at the laboratory by phone or email when you plan to send the samples.

8.0 Gender

All women will be provided with a copy of the women's questionnaire to self complete in the assessment area. Before the woman leaves this questionnaire should be checked Following the interview women who are still experiencing menstrual cycles will be given a reply paid postcard to post to the study centre on the first day of their next period so that time in cycle on the day of the test can be assessed.

Serum samples will be stored for measurement of sex hormones. Final decisions of hormones to be included will be made when the number of samples and age distribution of participants is known but these will include sex hormone binding globulin, testosterone, dehydroepiandosterone sulphate, follicle stimulating hormone and oestradiol.

Allergic outcomes and lung function will be assessed against reported menopausal status, reported gynaecological morbidity and serum levels of sex hormones in women having adjusted for age. In men the association of allergic outcomes and lung function with sex hormone levels will be assessed having adjusted for age and other determinants of sex hormone levels (in particular time of day of sample).

Ethical issues

All subjects will be asked to provide a blood sample from which serum will be taken and stored. At the time of consent participants will not know exactly which hormone measures will be made or which laboratory this will be done at. Participants will be asked for permission to a) store frozen serum, b) send frozen serum to a laboratory in Europe to have the serum tested and c) for these tests to include the measurement of sex hormones (for example; sex hormone binding globulin, testosterone, dehydroepiandosterone sulphate, follicle stimulating hormone, oestradiol) and other related hormones.

9.0 Food Frequency Questionnaire

9.1 General Objective

The nutrition questionnaires aim to assess the relationship between dietary patterns and allergy and asthma in adults from Europe.
The Food Frequency Questionnaire (appendix 20) was specifically designed taking into account the above mentioned objectives. In its design we took into account that the FFQ has to be simple enough to be understood and answered by the study participants independently. All centres are required to supply subjects with a Food Frequency Questionnaire, in advance of the appointment. The subject is required to complete the FFQ and bring it to the appointment with them.

9.2 TRANSLATIONS

Standardised translation procedures will be used to ensure that all centres collect the same data.
Questionnaire translation incorporates 2 main stages:

- forward translation (from English into local language)
- backward translation (comparison and any necessary editing)

A pilot of the translation is optional.

The English dietary questionnaires are the final versions sent to the Centres and the source documents. They are written in UK English and have been provided by the co-ordinating centre as Word documents. Forward translation into local language should follow the following procedure (Figure 1).

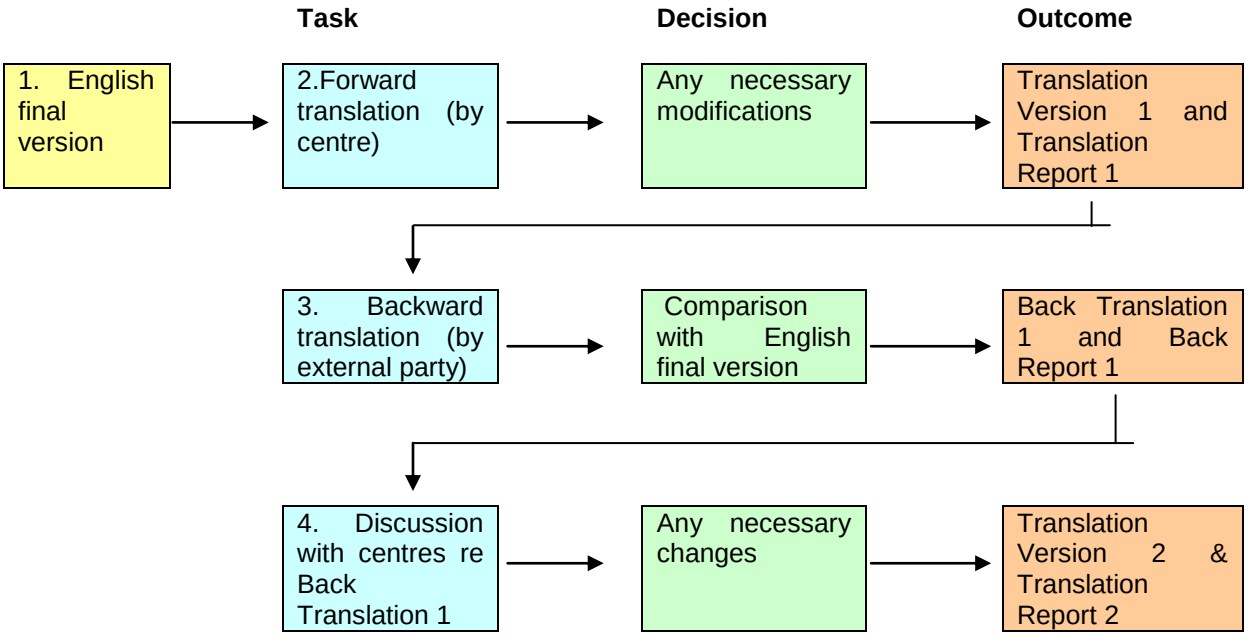
1) Recruit a local translator (native target language and bilingual UK English), this could be a member of the study team.
2) The translator produces 'Translation version1'. This should be a conceptual equivalent of the English final version document, in colloquial language and easy to understand.
3) If local centre staff (with or without the translator) assess that 'Translation version 1' needs modification then 'Translation version 1.1' incorporating any changes should be produced.

4) Centre staff should produce Translation report 1 and send to the co-ordinating centre (London) with Translation version 1 and (if appropriate) Translation version 1.1. These can be sent to Vanessa Garcia-Larsen (v.garcialarsen@imperial.ac.uk)

5) The translated documents should be in editable electronic formats compatible with Microsoft Word. The translation report 1 should describe how the translation was produced and outline (question by question) any issues that have arisen so far.

Once the "Translation Version 1" has been produced, centres are asked to arrange for back translations to be undertaken locally. It is very reasonable that a member of the study team undertake the forward translation, however, the back translation must be undertaken by a different person and someone completely unrelated to the work of the centre. They should not have specialist knowledge of the survey work.

Figure 1: Flow chart of translation process


Task
Decision
Outcome
1. English final version
2.Forward translation (by centre)
Any necessary modifications
Translation Version 1 and Translation Report 1
3. Backward translation (by external party)
Comparison with English final version
Back Translation 1 and Back Report 1
4. Discussion with centres re Back Translation 1
Any necessary changes
Translation Version 2 & Translation Report 2

The back translator should not have access to the original English final version while producing the translated questionnaire in English labelled 'Back translation 1'. Centres are asked to compare Back translation 1 with the English final version and produce Back report 1 identifying any misunderstandings or inaccuracies in Translation version1 (or Translation version1.1). Back report 1 should also state the main occupation of the back translator. Please transfer Back translation 1 and Back report 1 to **v.garcialarsen@imperial.ac.uk**

Co-ordinating centre staff will confer with centre staff (if possible the forward translator) to negotiate changes to Translation version 1 (or 1.1).

Following these discussions the centre should produce Translation version 2 and Translation report 2. Translation report 2 should be in English and detail the changes made to Translation version 1 with the preferred target language expressions and their English equivalents.

Following submission of the dietary questionnaires as "Translation version 2", centres may then make copies and use it in the piloting and in the follow-up survey.

At present, the FFQ has been translated into 7 languages: English, Greek, Spanish, Portuguese, German, Polish and Finnish (See Appendix 20). These are the "Translation version 1" of the FFQ, and centres are currently working in the Report 1 before starting the back translations.

Section 10 Questionnaire Administration

Before administering the questionnaire, each interviewer should become familiar with each question, coding and skips. It is important for interviewers to understand why a question has been asked and its meaning. Possible difficulties should be identified and discussed during the training session. The main questionnaire (Appendix 1) is to be administered as a face-to-face interview during the clinical visit.

The 'Inhaled steroid dose table' (appendix 5), the instructions for the main questionnaire (appendix 1) and a copy of the ISCO-88 (ILO) codes (refer to Appendix 18) are also required to complete the Questionnaire.

It is best to check safety questions (Appendix 23) with the participant before they attend clinic. If the participant does nonetheless answer "yes" to any of the spirometry safety questions (questions s1 to s8), during the clinic visit do not proceed with spirometry. If the participant has taken inhaled medications in the period of time before the visit that they were instructed to withhold medications, continue nonetheless. If the subject has had a recent respiratory tract infection, very recent dental work, acute back pain or major chest or abdominal surgery (more than 3 months previously), or presents with any other issue that the study staff member is concerned may affect spirometry or adversely affect the participant; the clinic visit should be rescheduled.

Otherwise complete the main body of Questionnaire.

The use of a structured questionnaire to answer different research questions is to ensure that data are collected in a standardised manner. The reliability of the data collected depends on how the questionnaire is administered by interviewers, and therefore it is essential that the questions are asked in the same way by different interviewers at different centres. At the same time it is crucial to allow comparability between centres.

The interviewers will ask the questions exactly as they are, using the exact wording and order, as written on the survey questionnaire, avoiding any hints or verbal clues. A good interviewing technique is the one which brings the same results, even if it will be repeated at a different point in time or in a different place (Bowling, 2002).

10.1 The interviewer

The success of a research interview and the reliability of the data collected depend on who is administering the questionnaire. People may give different responses to the same question, to different interviewers. In order to minimise potential bias, it is therefore recommended to select trained, experienced interviewers.

A common problem with health research interviews is that the interviewer could bias the information collected. This occurs especially with interviewers with a medical background as they may be tempted

to give extra-explanations or hints to respondents, rather than simply read the questions exactly as they are written.

Exercise 1

Take 10 minutes and discuss the examples given below, in groups of 2 people. Reason between good and bad options.

Examples:

1.
"You have got an attack of asthma, haven't you?"
"Have you ever had an attack of asthma?"

2.
"Are you busy/free now?"
"I would like to talk with you about our survey."

3.
"Have you ever had eczema, this kind of allergy when your skin is itchy and appears immediately after you took a medicine, or eat a food, or used a hands cream, or used a new cleaning product to wash your plates?"
"Have you ever had eczema or any kind of skin allergy?"

Responses:

1.
Q1 is wrong because it leads to an answer.
Q2 is good because is neutral.

Austrian children living on a farm have less hay fever, asthma and allergic sensitization 2.
Q1 is wrong because will attract a negative answer.
Q2 is a good example because it encourages people to respond.

3.
Q1 wrong example because it gives a lot of different details which may confuse the respondent and bias the information collected.
Q2 good because is neutral

The ideal interviewer, either clinical or non-clinical staff, should be **neutral and non-judgemental!** Never surprised or disappointed, never approving or disapproving, never feeling embarrassed about personal questions, never asking leading questions but **sticking to the exact wording and order** as on the survey questionnaire.

The ideal interviewer:

- will have a clear understanding of the study
- **always neutral**
- able to establish a good rapport with a wide range of people
- good, sensitive listener
- motivated and motivating
- friendly, well mannered, positive, able to gain the respondent's trust
- committed, persevering
- clear voice, good hearing
- rapid and accurate in recording responses, having an legible hand writing
- able at making respondents happy with their participation
- appropriate age

10.2 Materials:

- questionnaire copies on paper, pencils/pens ready to be used
- list with names, addresses and labels with allocated study IDs to selected participants
- coding sheets

10.3 Face - to -face questionnaire administration tips

1. **Adhere to the questions' order and wording.**
2. Be as **neutral** as possible. In order to avoid the interviewer bias, interviewers should not suggest answers or ask extra questions and should not give supplementary explanations to help people to respond. Verbal or non-verbal clues or hints should be avoided. Respondents should never feel that a certain answer is expected.
3. If an interviewer personally knows a participant, this person should be passed to another interviewer in order to ensure confidentiality and anonymity.
4. The interviewer should be prepared for unexpected interruptions of the interview due to unexpected situations (i.e. someone entering the room).
5. If the respondent refuses to answer a question, don't try to persuade reluctant responders too much. That may increase the respondent's bias.
6. Fill in the responses at the moment people gave them. Never leave it for later!
7. If the respondent re-addresses a previous question at a later stage of the interview, the interviewer should record the comments and note which question they are relating to.
8. Repeat clearly and slowly the question if the respondent does not understand it, using the same wording as it is written on the standard questionnaire.
9. If the respondent does not understand a particular word, the only response the interviewer can give is "whatever that means to you". An alternative would be to ask the respondent to define the term he/she does not understand. If the given definition is good, the interviewer can say so and repeat the question. It is not a good idea for interviewers to give definitions or explanations on what a particular word means, as that may result in bias.
10. If the respondent does not understand the question even after it has been repeated, the answer will be coded as "No"
11. A "Don't know" response should differentiate from a genuine uncertainty and other possible reasons the respondent may hide (i.e. lack of understanding the question, diplomatic refusal). Difficult to sense but a good idea would be to repeat the question.
12. If a respondent starts to comment on something else, the interviewer can bring the respondent back to the point of interest and gently explain that the comment can be discussed at the end of the interview.
13. Never interrupt respondents before they have finished speaking. Allow enough time for response.
14. Follow the skips where indicated. It is important to jump over inapplicable questions and this will also save time.
15. Read questions clearly, at an appropriate volume and speed, and make sure that the responses are accurately recorded.
16. If a respondent is not sure or does not know what to answer, tick "No".
17. In case of a refusal, try to encourage participation by being friendly and polite, offer to start the questionnaire and see how things go, gain trust by giving more of an explanation about the study goals, ethical approval and the time required for the interview.
18. If a respondent does not want to reveal personal information such as date of birth, the interviewer should re-confirm that this is confidential and the research goal is to assess the proportion of people suffering with allergic diseases in general and not necessarily to look at individuals' data. If the respondents remain reluctant, then their wishes should be respected.
19. Verbatim notes can be made on the respondents' comments. However, respondents should be reminded that they should answer with "Yes" or "No" only.

The golden rules for administering the study questionnaires through face-to-face interviews:

1. **Read the questions exactly as they are written on the questionnaire.**
2. **Do not give any extra-explanations or verbal or non-verbal clues even if the respondent is asking you or does not understand the question.**
3. **Emphasize the words written in bold and underlined.**
   If the respondent is unsure of the answer please tick 'NO'.

Section 11 Data management

11.1 Overview of data management at centres

- Study documents and data are transferred via the secure GA²LEN Survey Web pages.
- Personal data such as names and addresses must be kept separate from data collected in the study.
- The sample derived from the sampling frame for this clinical visit should be entered on a local password protected computer.
- Selected sample should keep the unique ID numbers attributed during the GA^{2}LEN Survey
- Centres have been allocated a range of 10,000 sequential six-digit numbers from which unique subject ID numbers can be drawn. The range will not overlap between centres.
- All centres are asked to test their data entry system using 5 supplied questionnaires before data entry begins.
- The co-ordinating centre will review the test file and feedback on any issues arising. Once the test has been reviewed, data entry can begin.
- At least daily backups should be kept of all data entered.
- Study subjects' names and addresses should not appear on any transferred data.
- Each completed questionnaire will be **double entered** locally using standard data entry forms and the data transferred to the Website.
- On completion of study a transfer master file will be sent to the co-ordinating centre,
- Final analysis of the data will be undertaken by the co-ordinating centre.

11.2 Sample codes

The sample ID code identifies some characteristics of the sample from which each subject was drawn.

1 = Participants identified from a general population register list (referent)
2 = Selected as asthmatic
3 = Selected as sinusitis

11.3 Data entry

11.3.1 Instructions for using Epidata

To ensure that all centres are collecting and entering data in the same way it is recommended that we all use the software package Epidata. Epidata is a very simple package that can be used for data

entry. It can be downloaded from the internet free of charge and has versions in many different languages, although these instructions are based on the English version.

The co-ordinating centre will produce the data entry files that will be used with the Epidata software. These files can be modified into local languages, though you may want to keep the files in English.
Although it is recommended that you use Epidata for entering your data you can choose to use your own system for entering data, e.g. using a database such as Access or scanning software linked to a database or spreadsheet. If you are not using Epidata you should ensure that you send your data in a format that can be read by the co-ordinating centre. In this case we recommend that you send your data as an Excel spreadsheet or a simple comma separated file, an Excel spreadsheet template will be provided to the interested partners and you should use these in your datasets. This list also includes the valid ranges of variables to help you clean your data if you are not using Epidata.

All instructions for downloading, installing and entering data should first be tested with the five dummy questionnaires attached to the manual (Appendix 12). You should also use these dummy questionnaires to test any alternative data entry package if you choose not to use Epidata.

11.3.2 Downloading and Installing Epidata
To download and install Epidata use the following instructions:

1. Go to site **http://www.epidata.dk**

2. Click on **Download (get files)** at the top of the page, this will take you to the download page.

3. Scroll down past **Epidata Analysis** to **Epidata Entry**.
Download the 4 English Language files – the flowchart, intro, Complete Setup and Extended help.

4. Run the .exe file on your computer, which will install Epidata.

There is the option to download Epidata in other languages but the instructions laid out in this document refer to English only. Feel free to download Epidata in your local language (if available) but remember that the instructions below apply only to the English version.

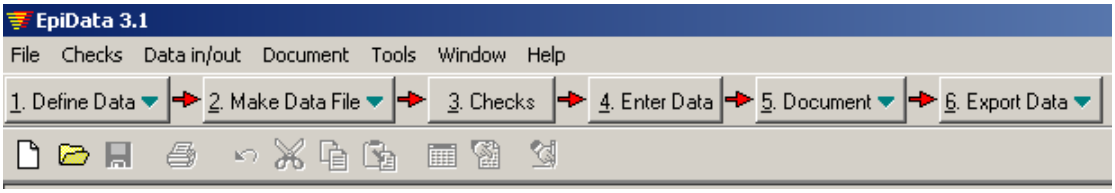
11.3.3 Setting up the data entry files in Epidata
The Questionnaire should be entered in Epidata using double-data entry, which is entering the data in two separate files and then comparing the two files for discrepancies. This ensures that data entry errors are kept to a minimum. Epidata makes both the entering of data and the validating of data very easy.

We have sent you two files that are used by Epidata in order to enter the data. These files are also available to download from the Survey Follow up pages of the Ga^{2}len website:

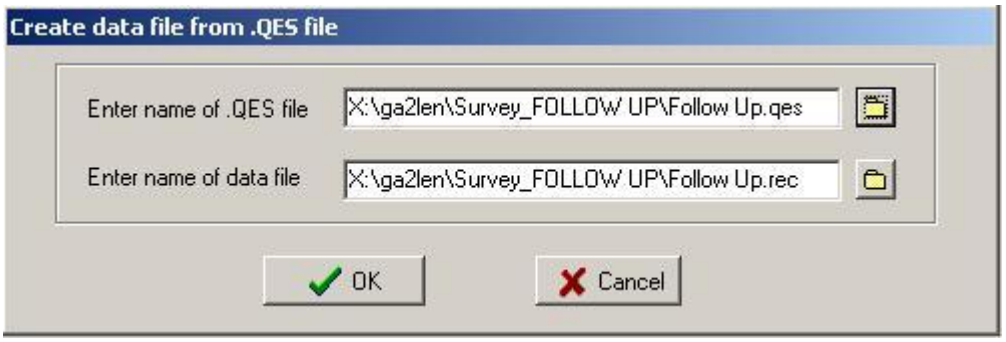
Followup.qes - file that creates the look of the form on the screen
Followup.chk - file that valid ranges are programmed within
In addition you will create through Epidata another file:
Followup.rec – file in which the participant data is entered

Open Epidata by double clicking on the Epidata icon. When you open Epidata a box will pop up saying "Welcome to Epidata" with information about the built-in help packages and tutorials. Feel free to read this information and even try the tutorials if you have time, however the instructions details below will aim to give you enough information to use Epidata for the purposes of this project.

Close the "Welcome to Epidata" box and you are presented with the following menus and options:



The next stage is to create the .rec file so that data entry can commence. To create the .rec file click on button *2, Make Data File*. Select the folder where you have placed the file *Followup.qes*. Click OK and the *Followup..rec* file will be created.

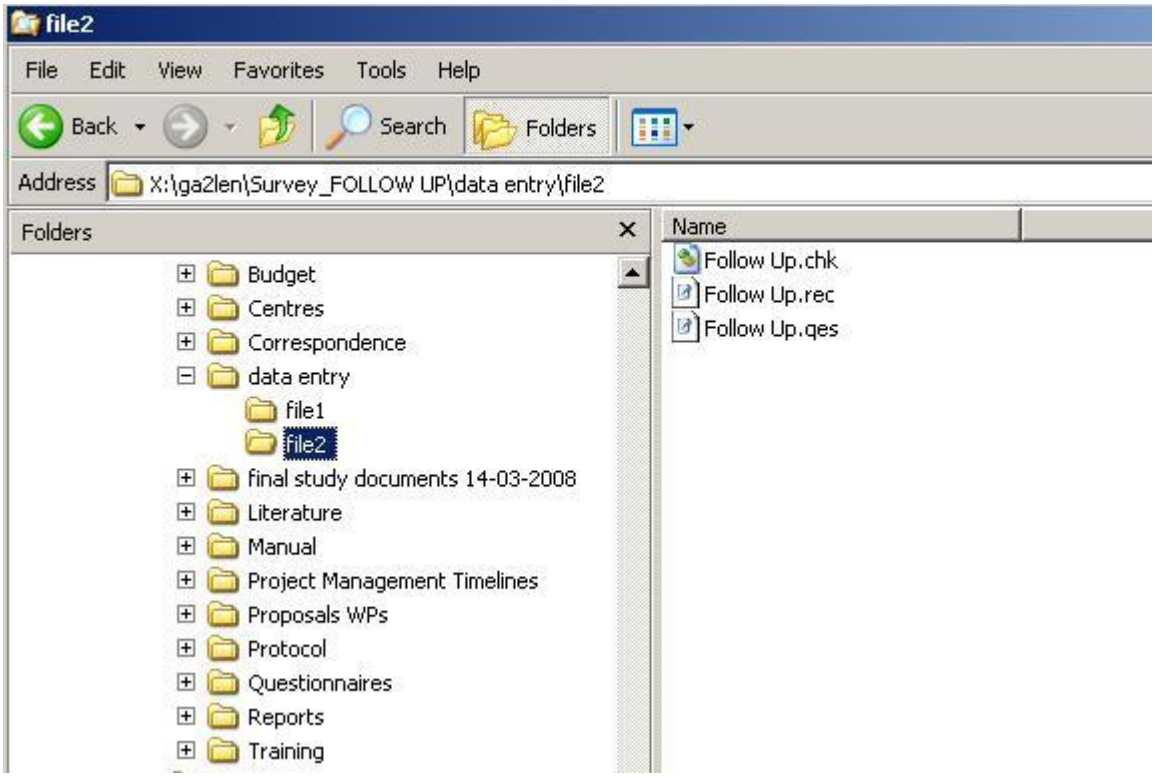


Repeat this process for the Food Frequency Questionnaire files, the Quality of Life questionnaire and the Women's Questionnaire.

11.3.4 Entering Your Data

Once you have created the *Followup.rec* file then you are ready to begin data entry. The *Followup.chk* that you have been sent does not need to be edited and this should work behind the scenes to ensure that no invalid data can be entered in any field. This file has to be in the same directory as the .qes and .rec file and have the same file name but with the .chk extension i.e. *Followup.chk*.

Since we are going to use double data entry, duplicate versions of the files you have just edited and created should also be created. It is recommended that you place the three original files in a sub-directory called "File 1" and then place copies of these files in an adjacent directory called "File 2". For example:



You are now ready to begin entering your data.

Click on button *4, Enter Data* and chose the file Followup.*rec* which you have just created. On the screen you will see the data entry form with boxes for you to enter data within.

Simply enter the data from the paper form in the fields. The data entry checks should ensure that no invalid entries are possible e.g.; it is impossible to enter a 3 in a field that should only have codes 1 or 2.

If you are unsure what codes are acceptable for a given field, simply click on that field and press F9, where a prompt box will pop up and give you the options. This should not be required very often since most questions are simply 'yes,' or 'no.'

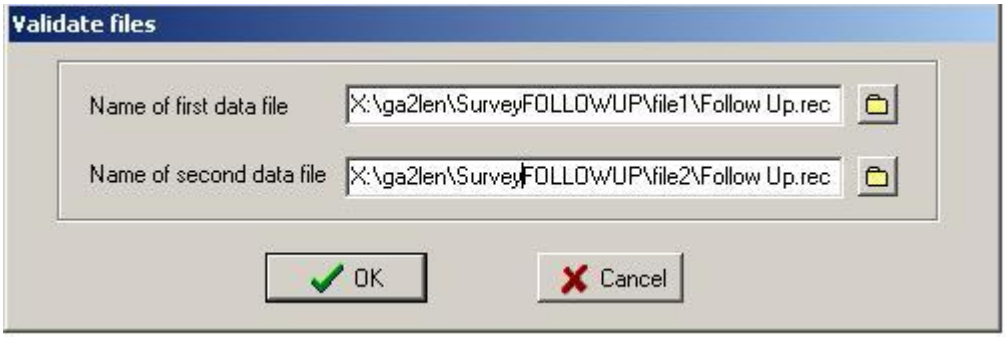
Once you have entered all the data from the first participant's questionnaire Epidata will prompt you to "save data to disk", to which you click "yes", saving that record and being presented with a new form with blanks fields ready for the next questionnaire.

You can tell how many forms you have entered by looking at the box in the bottom left hand corner of the screen – this box will say "New" followed by a backslash with the number of forms already entered e.g. if you've entered 5 forms already then this box will say "New/5".

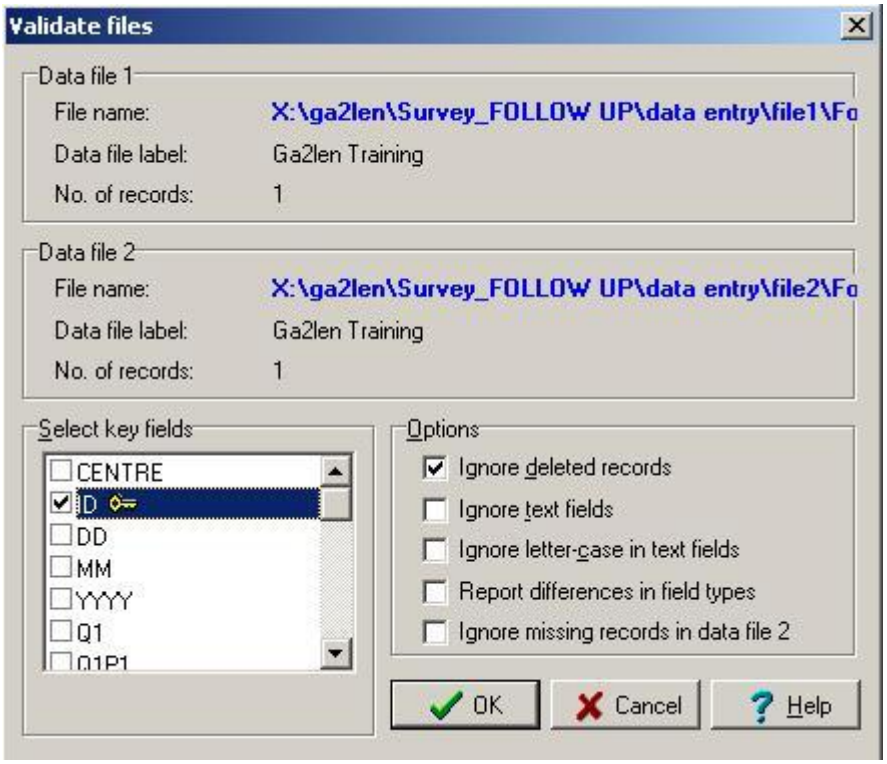
When you have entered all your data the directory File 1 you should then re-enter the data in the directory File 2. Preferably the data in File 2 will be entered by a different person from who entered the data in File 1, however this is not always practical and possible. You then should compare what has been entered in File 1 and File 2 for discrepancies.

11.3.5 Validating data

To validate the data, i.e. check that what has been entered in File 1 matches what has been entered in File 2, click on button *5 Document* and then click on *Validate duplicate files*. You will be presented with a pop up box with space to enter the names of two files, your original data file and your duplicate data file. Enter the file names and click OK.



This will lead you in turn to another box describing how many records are in each file, which should be the same since you have entered the same records in each file. This box also asks you to select the "key field" on which the files will be matched. Our key field is ID and this field should have a little key symbol already next to it. Click on the tick box next to ID and leave all the other options at their defaults. Then click OK and the validation will take place.



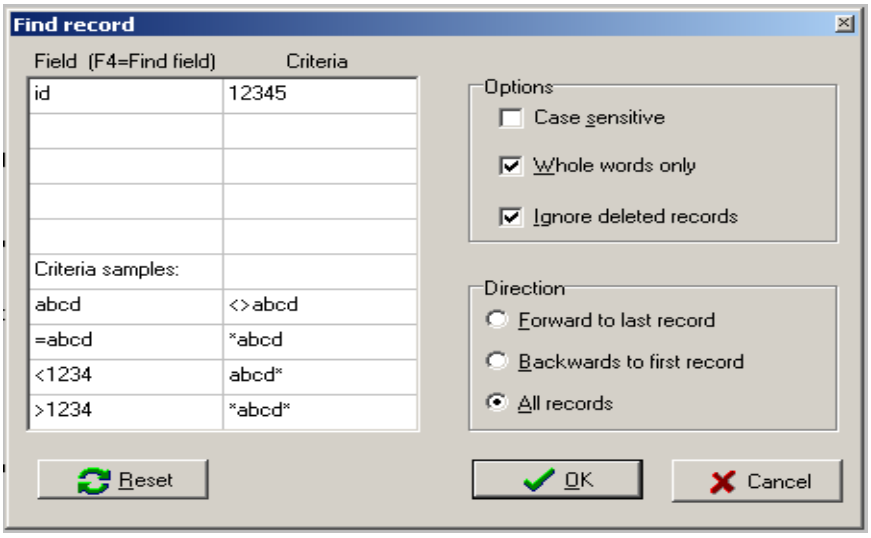
The validation process will display a validation report on the screen detailing the discrepancies between the entered data in File 1 and File 2 by ID number and question number. The validation report should be printed out. Hopefully there will be very few differences but there will be some. Any differences should be investigated by tracking back the original paper form for that ID to be discovered and identify the correct information written on the form. The correct information should then be entered on the Epidata file that has the wrong data.

11.3.6 Correcting Differences

To correct what is entered go back to button *4, Enter Data* in Epidata and choose the file that has incorrectly entered data. You can then either scroll back through the records to the forms or go directly to the forms

To scroll through the data use the arrow buttons in the bottom left hand corner of the screen to find the ID that you wish to change. To go directly to the ID place the cursor in the ID field and choose *"Goto"* from the menus at the top, then choose *Find Record*. Enter the ID number under the criteria column

(as shown below) and then click OK and Epidata will take you directly to the form for the ID number in question.



Simply go to the field where the incorrect data has been entered and change to the correct information. Continue until you have corrected all the wrong entries for all IDs. Then run the validation process once more and hopefully this time there will be no discrepancies. The validated and corrected data file should be transferred to the co-ordinating centre!

11.3.7 Variable Names and Coding
The list of variable names and codes can be found in Appendix 12.

11.3.8 Data Transfer
The main contact web –manager is Tom Vermetten. Email: **tom@custodix.com**

The main email address for the co-ordinating centre is j.potts@imperial.ac.uk or or m.tumilty@imperial.ac.uk or m.lim@imperial.ac.uk

Please do not send documents or data to these addresses.

The GA²LEN Survey Follow up Web facility at: **http://www.ga2len.net** should be used for secure transfer of data and other study documents. Appendix 11 contains a step-by-step user manual for the GA²LEN Follow up web pages. Please read this document carefully before accessing the site. Please name the transfer files as indicated.

Only users with a valid username and password are authorised to access the private GA^{2}LEN website. Each user can only view the modules that are registered for his account. Cross-site scripting attacks are prevented by the Cold fusion server. Updates or inserts in the database are done via stored procedures which prevent malicious SQL statements.

Survey collaborators gain access to the web pages after confirming their participation. Please inform the co-ordinating centre of the names and email addresses of the local survey coordinator.

If you are not yet registered to the GA^{2}LEN website, Appendix 10 gives instructions for doing so.

11.3.9 Follow up study files
Centres are asked to deliver 4 separate types files during and on completion of the clinical visit.

- The data entry test file

Produce this Epidata file to test the data entry system before starting data collection. It will check the integrity of the translated questionnaire, the translated Epidata form and the file transfer procedures. This file should be named data_entry_test.rec

- A report on sampling

Produce a brief report giving information about the sampling method, the response rate, when ID numbers were allocated, what sample codes have been used and the numbers of respondents. This file should be named data_collection_report.doc

- Epidata files

This will contain the **double entered and cleaned** Questionnaire data. The files should be named date_*centrename_questionnaire*.rec, e.g. 08_MAY_08_london_main.rec, 08_MAY_08_london_ffq.rec and 08_MAY_08_london_womens.rec

- Spirometry file

Centres will upload initially the first 10 spirometries for quality control check. This will be an Access database. The co-ordinating centre will do a quality check and feed-back to centres. Every 30 spirometries should be submitted as finished so regular quality control checks can be made and problems identified and solved. Only ndd spirometry database files (.mdb) can be uploaded to the spirometry folder. The mdb files uploaded to this folder must be renamed according to the date of transfer. Each time new data is added to your ndd EasyWare mdb file, copy it and rename it according to the following syntax:

DD_MMM_YY.mdb

e.g. 08_MAY_08.mdb

The folder will only accept files that are correctly named, it will only accept a file named according to the date of transfer. Transfer a maximum of one file per day.

- Study Master File

This file should list (in numerical order) subject IDs of all the respondents. These data should be stored and use in the follow-up studies. This file should be named master_file_*centre name*.xls

- Final linkage of the data will be undertaken at the co-ordinating centre.

Important note: Any data transferred outside centre must not contain any personal information of study participants (name, address). Personal data should be kept separate from transferred data

Section 12 Quality control

12.1 Survey Follow Up QC

A major motivation for this work is to allow us to demonstrate the ability of the GA^{2}LEN network to execute a co-ordinated integrated research project.

The Follow up study will measure the extent to which each of the centres can achieve several outcomes including:

- Administration of a common screening questionnaire
- Adequate translation of the common questionnaire
- Common training of study staff
- Drawing of adequate cases and referents
- Execution of a common interview and examination schedule of:
    - an administered questionnaire
    - lung function tests
    - blood sampling
    - testing for atopy
- Submission of high quality data for central analysis

These activities will be undertaken in a wide variety of settings in over 20 different centres and will involve up to 10,000 participants. The Project quality control (QC) measures are vital to insure the integrity of the data and the quality of the work undertaken.

The Follow up study QC covers 5 main areas:

- Questionnaire Administration
- Data Entry
- Spirometry (and spirometry data transfer)
- Skin Prick testing
- Blood Sample Processing

Centres are asked to implement the QC procedures described below and clearly document that they have done so.

12.2 Study training

All Project centres are asked to attend a training session before the commencement of data collection. 2 project staff working effectively on clinical data collection from each centre should attend the workshop (i.e. research nurses). Study protocols and SOPs will be examined and the standardised techniques demonstrated. Only members of staff who will be involved in the study will be able to attend the training. There will be no time for a local investigator(s) to attend the initial training and to disseminate the training to other study staff at the centres later on.

The training sessions and centre-led training will address the main QC areas:

12.3 Questionnaire administration

There are 3 quality control activities related to questionnaire administration:

1) Completion of the forward and back translation procedures for Questionnaire before submission for Ethical Approval
2) Completion of the central training
3) Check filled questionnaires for errors, missing data, accuracy of record, over-consistent responses

Staff from each centre are required to review the questionnaires, the instructions and the ISCO-88 coding system before the training and identify any initial queries. The training will involve a detailed review of the questions and the instructions. There will also be discussion about general good practice in questionnaire administration. Instructions for hard copy questionnaire administration will be reviewed.

Only staff that have completed central training should administer Questionnaires. Experienced interviewer is also required to undergo training to follow the questionnaire instructions based on protocol. **If interviewers have received formal medical training it is particularly important that they are trained to guard against interpreting participants' responses.**

The answers to questions 24.2, on the Main Questionnaire and questions 18.5, 18.9, 21.1, 23.1 in the further question section must be coded using the 1988 International Standard Classification of Occupations. This can be done for the entire data set at the end of data collection or individually after each participant visit. Ideally the person who administered the questionnaire should code the answers. Nonetheless, it is important that interviewers are familiar with the ISCO classification system to ensure adequate data are collected for good quality coding.

Only centrally trained individuals will be collecting data, so there is no need to train others

12.4 Data Entry

Centres are asked to use a double entry system and will be supplied with English language Epidata entry files with specified variables.

There are 3 quality control activities related to data entry are:

1) Completion of the entry test: transfer of 5 dummy completed questionnaires provided by the co-ordinating centre (see chapter 12) and 10 real postal survey questionnaires
2) Correct coding where applicable
3) Double entry of the questionnaire responses

Procedures for data entry and transfer will be fully addressed during the initial training workshops. During the training sessions, centres will be given 5 (translated if necessary) completed versions of each questionnaire. On return to the centre they are asked to enter the data using the programme and method they will use during the study. This must be undertaken in the language to be used during data entry. In particular, if the Epidata data entry forms are to be translated locally, this must be done before the test is carried out. Answers to question requiring coding need to be completed and any free text answers to question with this option should be translated into English. Once entered the test file should be transferred to the Website. This 'dummy run' will allow all parties to check for potential problems with data entry and transfer of the data. All problems should be identified and rectified at this point.

No study data should be entered or transferred until the test dummy run has been carried out and discussed with the co-ordinating centre

Ideally, the person who will be responsible for data entry and file transfer at the centre should be the person who carries out the dummy run. If this is not possible the person who has carried out the dummy run should personally train the member of staff in the correct procedures before they begin any data entry. The Epidata data entry files have built in quality checks and appendix 11 also provides instructions for basic data leaning.

To complete the dummy-run centres will need to have access to the study Website. Access is given to those who have attended central training or those whom have been appropriately trained locally.

Centres using PC-assisted questionnaire administration are asked to transfer a copy of the Epidata file to the Website after the first 10 visits have been undertaken, so that the progress of the data entry can be reviewed. If there are no problems arising, data collection should continue and the completed Epidata Questionnaire file transferred to the Site at the end of data collection.

12.5 Spirometry (and spirometry data transfer)

The initial training sessions will include training in the use of the EasyOne spirometer. This will include discussion on participant coaching techniques, methods for measuring height and weight and correct spirometry data transfer procedures.

Staff that will undertake the spirometry data collection should attend the initial training session. The spirometry QC system will allow for close review of the data collected by all staff. The co-ordinating centre will monitor and provide periodic feedback on each staff member's performance during data collection. If there are any specific quality issues or if QC scores are inadequate these should be addressed locally, normally through revisiting aspects of the training.

EasyOne internal guidance messages

Parameter	**QC message**
BEV > 150mL	*don't hesitate*
PEFT > 120ms	*blast out faster*
FET < 2sec	*blow out longer*
dPEF > 1 L/s	*blast out harder*
dFEV1 > 150mL	*deeper breath*
dFEV6 > 150mL	*deeper breath*

Test session quality grades

A 3+ acceptable, best 2 dFEV1 and dFVC <150ml
B 3+ acceptable, best 2 dFEV1 and dFVC <200ml
C 2+ acceptable, best 2 dFEV1 and dFVC <250ml
D 2 acceptable maneuvers, but not reproducible (or one acceptable)
F no acceptable maneuvers

The co-coordinating centre will review the best 3 curves of each session for individual curve quality
Collaborating staff are asked to maintain an average score of at least 3.0 score (4=A, 3=B, 2=C, 1=D, 0=F)

Common factors affecting spirometry quality:

Participant: A subject may not take as deep a breath as possible or exhale as forcefully as possible at the start of the manoeuvre. Several possibilities will prevent a manoeuvre from being acceptable: an involuntary epiglottis closure, temporarily cutting off the flow of air; an early termination of the manoeuvre', or a variable effort. Coughing during the manoeuvre or a leakage due to the participant's inability to keep a tight seal will also adversely affect a manoeuvre.

To address this source of error, it is very important to train staff to watch the participant closely during the performance and accurately review the displayed flow-volume curves on the computer monitor. Staff can then explain the errors and offer the participant further guidance.

Staff: Poor coaching or non-standardized coaching procedures will negatively affect the quality of the spirometry testing. Study staff should clearly instruct the participant on how to perform this test, demonstrate the manoeuvre, and watch the participant closely during the performance to avoid errors and obtain the best effort. S/he must be trained to recognize patterns of unacceptable manoeuvres and perform equipment checks. The co-ordinating centre will monitor and provide periodic feedback on each staff member's performance.

Equipment: Leaks in the system, differences in temperature, and poor calibration are all factors that affect the quality of the test results. Daily spirometer calibration checks should be performed using a 3.00 litre syringe. Refer to section 14 of the EasyGuide users' manual for instructions.

12.6 Skin Prick testing
Training in the SOP for the allergy skin sensitivity tests will be covered in the initial training session.

Only centrally trained individuals will be collecting data, so there is no need to train others

12.7 Sample Processing
The sample collection and processing procedures will be reviewed during the initial study training. It is vital that samples are correctly and clearly labelled and that the barcode stickers are not obscured. It is also important that centres keep careful records of the stored samples in their sample logbook and that copies of the logbook are sent with the samples during shipment.

Centres are advised to review the sample logbook intermittently to ensure that it compares correctly to the stored samples and against appointment records indicating which subject should have stored samples.

The samples and logbook will ultimately be compared to the sample collection data recorded in Main Questionnaire/ Results sheet.

Section 13 Communications

Various communication methods will be used including telephone conference calls, e-mailing and Web posting of study documents and reports. Urgent communications should be made by telephone or email. The main email address for the co-ordinating centre is **m.lim@imperial.ac.uk** Please do not send documents or data to this address.

The GA²LEN Survey Web facility at: **http://www.ga2len.net** should be used for secure transfer of data and other study documents. Appendix 11 contains a step-by-step user manual for the Survey web pages. Please read this document carefully before accessing the site.

Where e-mail or Website linkage is temporarily unavailable, arrangements can be made to transfer documents and data by mail and secure fax.

13.1 Contact details for co-ordinating centre

Contact Person	Name	Telephone	email
Work Package Leader	Peter Burney	+44(0)207 352 8121 ext. 3506	p.burney@imperial.ac.uk
Study Co-ordinator	Ms Mun Lim	+44(0)207 352 8121 ext. 3503	m.lim@imperial.ac.uk
Research statistician and data manager	James Potts	+44(0)207 352 8121 ext. 3521	j.potts@imperial.ac.uk
Researcher	Michael Tumilty	+44(0)207 352 8121 ext. 3501	m.tumilty@imperial.ac.uk

13.2 GA²LEN Survey Partners

Centre	Contact	Email
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University of Genoa, Italy	Prof. Giorgio Walter Canonica	canonica@unige.it
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University Medical University of Lodz MUL Poland	Prof. Marek Kowalski	Marek.kowalski@csk.am.lodz.pl
Universitad de Coimbra, Portugal	Prof. Ana Todo-Bom	Flcosta@netcabo.pt
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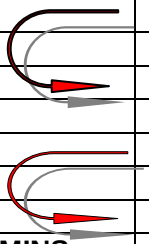
Pulmonology Research Institute of the Federal Medicobiological Agency of Russia	Alexander G. Chuchalin	chuchalin@inbox.ru
Institute of Immunology of the Federal Medicobiological Agency Russia	Natalia I. Ilyina	**instimmun@yandex.ru**
RAMS Children's Health Research Centre, Moscow	NAMAZOVA Leyla S.	**namazova@nczd.ru**

13.3 Clinical visit process

TIME TAKEN	CLINICAL VISIT PROCESS
3	Welcome and consent
3	Height, weight, waist and hip measurements
3	PNIF test
10	SMELL test
15	Maximum post bronchodilator test
20	Questionnaire administration
10	Final lung function test
5	Phlebotomy – blood taking
10	Skin prick testing (set timer for 15 minutes)
5	Check self administered questionnaires (FFQ & EuroQOL)
10	Obtain skin prick test results
94 MINS	Provide women with a copy of women's questionnaire to complete before the end of clinic visit. Alternatively they can also return the completed questionnaire in a pre paid envelope supplied.



13.4 References

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Green J, Browe J, Principles of Social research, Cap. 12 Survey design, pp.116-127, Open University Press UK, 2005

Department of Public Health Sciences, ECHRS II Protocol, King's College London, UK, 2003

Clement Clark, online at: http://www.clementclarke.com/products/inspiratory_flow/in-check_nasal/how_to_measure_pnif/index.html, last visited, 25th Oct, 2007

Wilson A, 2003, Airflow Obstruction and Peak Nasal Inspiratory Flow (PNIF), Published online by Clement Clark at: http://www.clementclarke.com/products/inspiratory_flow/in-check_nasal/pnif_review/index.html, last visited 25th Oct 2007

WP 1.2.1

GA²LEN SURVEY FOLLOW UP

Manual of Procedures

Appendices

Version 2.0

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2. EuroQOL Quality of Life Questionnaire and instructions
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8. Consent Forms
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Appendix 1: Follow up Main Questionnaire

Barcode ticker…….

I AM GOING TO ASK YOU SOME QUESTIONS. AT FIRST THESE WILL BE MOSTLY ABOUT YOUR BREATHING. WHEREVER POSSIBLE, I WOULD LIKE YOU TO ANSWER 'YES' OR 'NO'.

1. Have you had wheezing or whistling in your chest at any time in the last ***12 months***? NO ☐ YES ☐
   IF 'NO' GO TO QUESTION 2, IF 'YES':

   1.1 Have you been at all breathless when the wheezing noise was present? NO ☐ YES ☐

   1.2. Have you had this wheezing or whistling when you did ***not*** have a cold? NO ☐ YES ☐

2. Have you woken up with a feeling of tightness in your chest at any time in the last ***12 months***? NO ☐ YES ☐

3. Have you had an attack of shortness of breath that came on during the day, when you were at rest, at any time in the last ***12 months***? NO ☐ YES ☐

4. Have you had an attack of shortness of breath that came on ***following*** strenuous activity at any time in the last ***12 months***? NO ☐ YES ☐

5. Have you been woken by an attack of shortness of breath at any time in the last ***12 months?*** NO ☐ YES ☐
   IF 'NO' GO TO Q6, IF 'YES':

   5.1 Have you been woken by an attack of shortness of breath in the last ***3 months***? NO ☐ YES ☐
   IF 'NO' GO TO Q6, IF 'YES':

      5.1.1 ***On average*** have you been woken by an attack of shortness of breath ***at least once a week*** *in the* ***last 3 months?*** NO ☐ YES ☐
      IF 'NO' GO TO Q6, IF 'YES':

         5.1.1.1 How many times a week ***on average*** have you been woken by shortness of breath in the ***last 3 months***? TIMES ☐☐

6. Have you been woken by an attack of coughing at any time in the ***last 12 months***? NO ☐ YES ☐

7. Do you ***usually*** cough first thing in the morning in the winter? NO ☐ YES ☐
   [IF DOUBTFUL, USE QUESTION 8.1 TO CONFIRM]

8. Do you ***usually*** cough during the day, or at night, in the winter? NO ☐ YES ☐
   IF 'NO' GO TO QUESTION 9, IF 'YES':

   8.1 Do you cough like this on most days for as much as three months each year? NO ☐ YES ☐

9. Do you ***usually*** bring up any phlegm from your chest first thing in the morning in the winter? **[IF DOUBTFUL, USE QUESTION 10.1 TO CONFIRM]** NO ☐ YES ☐

NO YES

10.Do you ***usually*** bring up any phlegm from your chest during the day, or at night, in the winter? ☐ ☐

'NO' GO TO QUESTION 11, IF 'YES':

NO YES

10.1 Do you bring up phlegm like this on most days for as much as three months each year? ☐ ☐

NO YES

11. Are you disabled from walking by a condition ***other than*** heart or lung disease? ☐ ☐

IF 'YES' STATE TYPE OF CONDITION IN THE BOX BELOW AND GO TO QUESTION 12, IF 'NO' GO TO Q11.1:

a) bone and joint problems	a ☐
b) neurological including stroke	b ☐
c) vascular including amputations	c ☐
d) accidents	d ☐
e) other	e ☐
NOW GO TO Q12	☐

NO YES

11.1 Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? ***IF 'NO' GO TO QUESTION 12, IF 'YES':*** ☐ ☐

NO YES

11.1.1 Do you get short of breath walking with other people of your own age on level ground? ***IF 'NO' GO TO QUESTION 12, IF 'YES':*** ☐ ☐

NO YES

11.1.1.1 Do you have to stop for breath when walking at your own pace on level ground? ☐ ☐

NO YES

12. Have you ***ever*** had asthma? ☐ ☐

IF 'NO' GO TO QUESTION 13, IF 'YES':

NO YES

12.1 Was this confirmed by a doctor? ☐ ☐

YEARS

12.2 How old were you when you had your first attack of asthma? ☐☐

YEARS

12.3 How old were you when you had your most recent attack of asthma? ☐☐

NO YES

12.4 Have you had an attack of asthma in the last ***12 months***? ☐ ☐

IF 'NO' GO TO 12.7, IF' YES':

ATTACKS

12.5 How many attacks of asthma have you had in the last ***12 months***? ☐☐

IF 'NONE', GO TO 12.7, IF 'YES':

ATTACKS

12.6 How many attacks of asthma have you had in the last ***3 months***? ☐☐

12.7 How many times have you woken up because of your asthma in the last ***3 months?*** TICK ONE BOX ONLY

a) every night or almost every night	a ☐
b) more than once a week, but not most nights	b ☐
c) at least twice a month, but not more than once a week	c ☐
d) less than twice a month	d ☐
e) not at all	e ☐

12.8. How often have you had trouble with your breathing because of your asthma in the last ***3 months?***

TICK ONE BOX ONLY

a) continuously	a ☐
b) about once a day	b ☐
c) at least once a week, but less than once a day	c ☐
d) less than once a week	d ☐
e) not at all	e ☐

	NO	YES
12.9 Are you currently taking any medicines including inhalers, aerosols or tablets for asthma?	☐	☐

	NO	YES
13. Do you have any nasal allergies, including hay fever?	☐	☐

IF 'NO' GO TO Q14, IF' YES':

	YEARS
13.1 How old were you when you first had hay fever or nasal allergy?	☐☐

	NO	YES
14. Have you ***ever*** had a problem with sneezing, or a runny or a blocked nose when you did not have a cold or the flu?	☐	☐

IF 'NO' GO TO Q17, IF 'YES':

	NO	YES
14.1. Have you had a problem with sneezing or a runny or a blocked nose when you did not have a cold or the flu ***in the last 12 months***?	☐	☐

IF 'NO' GO TO Q15, IF' YES':

	NO	YES
14.1.1. Has this nose problem been accompanied by itchy or watery eyes?	☐	☐

14.1.2. In which months of the year did this nose problem occur?	NO	YES
January	☐	☐
February	☐	☐
March	☐	☐
April	☐	☐
May	☐	☐
June	☐	☐
July	☐	☐
August	☐	☐
September	☐	☐
October	☐	☐
November	☐	☐
December	☐	☐

14.1.3. Is this set off by:	NO	YES
Grass pollen	☐	☐
Tree pollen	☐	☐
Weed pollen	☐	☐
Moulds	☐	☐
Animals	☐	☐
Perfumes, smells or smoke	☐	☐
Changes in the temperature	☐	☐
Changes in position (such as lying down)	☐	☐

	NO	YES
15. ***In the last 5 years*** have you used any medication to treat problems in your nose, or hayfever?	☐	☐

16. In the last 5 years have you ever used **nasal** steroids? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 17 IF 'YES':

16.1. How old were you when you first started to use **nasal** steroids? YEARS ☐☐

16.2. Have you used **nasal** steroids ***every year*** in the last 5 years? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 16.3, IF 'YES':

16.2.1. On average how many months each year have you taken them? MONTHS ☐☐
NOW GO TO Q17

16.3 How many of the last 5 years have you taken **nasal** steroids? YEARS ☐☐

16.4. On average how many months of each of these years have you taken them? MONTHS ☐☐

17. In the last 5 years have you ever used **antihistamine tablets, medicines, nasal sprays or eye drops?** *IF NO, GO TO QUESTION 18* NO ☐ YES ☐

17.1. How old were you when you first started to use these **antihistamines**? YEARS ☐☐

17.2. Have you used these **antihistamines *every year*** in the last 5 years? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 17.3, IF'YES':

17.2.1. On average how many months each year have you taken them? MONTHS ☐☐
NOW GO TO Q18

17.3 How many of the last 5 years have you taken **antihistamines**? YEARS ☐☐

17.4. On average how many months of each of these years have you taken them? MONTHS ☐☐

18. Has your nose been blocked **<u>for more than 12 weeks during the last 12 months?</u>** NO ☐ YES ☐
IF 'NO' GO TO Q19, IF 'YES':

18.1 How old were you when you first had this symptom? YEARS ☐☐

18.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

19. Have you had pain or pressure around the forehead, nose or eyes **<u>for more than 12 weeks during the last 12 months</u>?** NO ☐ YES ☐
IF 'NO' GO TO Q20, IF 'YES':

19.1 How old were you when you first had this symptom? YEARS ☐☐

19.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all a ☐
b) Less than once a week b ☐
c) At least once a week, but less than once a day c ☐
d) About once a day d ☐
e) Continuously e ☐

NO ☐ YES ☐

20. Have you had discoloured nasal discharge (snot) or discoloured mucus in the throat **for more than 12 weeks during the last 12 months?**

IF 'NO' GO TO QUESTION 21, IF 'YES':

YEARS ☐☐

20.1 How old were you when you first had this symptom?

20.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all a ☐
b) Less than once a week b ☐
c) At least once a week, but less than once a day c ☐
d) About once a day d ☐
e) Continuously e ☐

NO ☐ YES ☐

21. Has your sense of smell been reduced or absent **for more than 12 weeks during the last 12 months?**

IF 'NO' GO TO QUESTION 22, IF 'YES':

YEARS ☐☐

21.1 How old were you when you first had this symptom?

21.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all a ☐
b) Less than once a week b ☐
c) At least once a week, but less than once a day c ☐
d) About once a day d ☐
e) Continuously e ☐

NO ☐ YES ☐

22. Have you had mucus in your throat **for more than 12 weeks during the last 12 months**?

IF 'NO' GO TO QUESTION 23, IF 'YES':

YEARS ☐☐

22.1 How old were you when you first had this symptom?

22.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all a ☐
b) Less than once a week b ☐
c) At least once a week, but less than once a day c ☐
d) About once a day d ☐
e) Continuously e ☐

NO ☐ YES ☐

23. Has a doctor ***ever*** told you that you have **chronic** sinusitis or nasal polyps?

IF 'NO' GO TO QUESTION 24, IF 'YES':

YEARS ☐☐

23.1 How old were you when you first had sinusitis OR nasal polyps?

YEARS ☐☐

23.2 How old were you when you were first diagnosed as having chronic sinusitis OR nasal polyps?

23.3. How did your sinus problems start? TICK ONE BOX ONLY

a) Headache or pressure over the sinuses	a ☐
b) Loss of smell	b ☐
c) A common cold	c ☐
d) Frequent episodes of acute sinusitis	d ☐
e) None of the above	e ☐

23.4 If you also get asthma, how does this relate to your sinus problems? TICK ONE BOX ONLY

a) I don't get asthma	a ☐
b) Sinusitis usually comes before the asthma worsens	b ☐
c) Asthma usually comes before the sinusitis worsens	c ☐
d) Both usually start with a common cold	d ☐
e) None of the above	e ☐

23.5 If you drink alcohol does this worsen your sinus problems? NO ☐ YES ☐ N/A ☐

23.5.1 - 4 ***IF 'NO' or N/A, skip to 23.6 ; IF 'YES', which symptoms does alcohol affect?***

	NO	YES
23.5.1 Blocked Nose	☐	☐
23.5.2 Runny Nose	☐	☐
23.5.3 Post nasal drip (mucus in the throat)	☐	☐
23.5.4 Sneezing	☐	☐

23.6 Have you ***ever*** had surgery for nasal/sinus problems? NO ☐ YES ☐

23.7. In the last 5 years have you ever used **antibiotics for nasal/sinus problems**? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 24

23.8. How old were you when you first started to use **antibiotics for nasal/sinus problems**? YEARS ☐☐

23.9. Have you used **antibiotics for nasal/sinus problems *every year*** in the last 5 years? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 23.10, IF 'YES':

23.9.1. On average how many months each year have you taken them? MONTHS ☐☐
NOW GO TO Q24

23.10 How many of the last 5 years have you taken **antibiotics for nasal/sinus problems**? YEARS ☐☐

23.11. On average how many months of each of these years have you taken them? MONTHS ☐☐

24. Have you ***ever*** had eczema or any kind of skin allergy? NO ☐ YES ☐
IF 'NO' GO TO Q25, IF 'YES':

24.1. Was this problem ***ever*** associated with your work? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 25, IF 'YES':

24.2. What job were you doing that made it worse? ☐☐☐☐
_____

NO YES

24.3. Do you know what caused the problem at work? ☐ ☐

IF 'YES' What was this problem?_____

NO YES

25. Have you ***ever*** had an itchy rash that was coming and going for at ***least 6 months***? ☐ ☐

***IF 'NO' GO TO QUESTION 26, IF 'YES'*:**

NO YES

25.1. Have you had this itchy rash ***in the last 12 months?*** ☐ ☐

IF 'NO' GO TO QUESTION 26, IF 'YES':

NO YES

25.1.1. Has this itchy rash ***at any time*** affected any of the following places: the folds of the elbows, behind the knees, in front of the ankles under the buttocks or around the neck, ears or eyes? ☐ ☐

NO YES

25.1.2. Does this itchy rash affect your hands? ☐ ☐

NO YES

26. Have you ***ever*** had any difficulty with your breathing after taking medicines? ☐ ☐

IF 'NO' GO TO QUESTION 27 IF 'YES':

26.1 Which medicines? _____ 26.1.1 ☐

26.1.2 ☐

NO YES

27. Have you ***ever*** had a runny or a stuffy nose or sneezing after taking medicines? ☐ ☐

IF 'NO' GO TO QUESTION 28, IF 'YES':

27.1 Which medicines? _____ 27.1.1 ☐

27.1.2 ☐

NO YES

28. Have you ***ever*** had uticaria, nettle rash or hives after taking medicines? ☐ ☐

IF 'NO' GO TO QUESTION 29, IF 'YES':

28.1 Which medicines? _____ 28.1.1 ☐

28.1.2 ☐

NO YES

29. Have you ***ever*** had an illness or trouble caused by eating a ***particular*** food or foods? ☐ ☐

IF 'YES' GO TO QUESTION 29.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

NO YES

29.1 Have you nearly always had the same illness or trouble after eating this type of food? ☐ ☐

IF 'YES' GO TO QUESTION 29.1.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

29.1.1 What type of food was this? [List up to 3]

_____29.1.1.1 ☐☐

_____29.1.1.2 ☐☐

_____29.1.1.3 ☐☐

29.1.2 Did this illness or trouble include:

	NO	YES
29.1.2.1. Itching, tingling or swelling in the mouth, lips or throat?		
29.1.2.2. A rash, nettle sting like rash or itchy skin?		
29.1.2.3. Diarrhoea or vomiting (other than food poisoning)?		
29.1.2.4. Runny or stuffy nose?		
29.1.2.5. Red, sore or running eyes?		
29.1.2.6. Difficulty swallowing?		
29.1.2.7. Breathlessness?		
29.1.2.8. Stiffness in your joints?		
29.1.2.9. Fainting or dizziness?		
29.1.2.10. Headaches?		

SOME FURTHER QUESTIONS

1. How old was your mother when you were born? YEARS ☐☐

2. Were you hospitalised before the age of two years for lung disease? NO ☐ YES ☐

Your parents' smoking

3. Did your father ***ever*** smoke regularly during your childhood? NO ☐ YES ☐ DON'T KNOW ☐

4. Did your mother ***ever*** smoke regularly during your childhood, or before you were born? NO ☐ YES ☐ DON'T KNOW ☐
IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 5, IF 'YES':

4.1 When your mother was pregnant, in particular with you, did she: TICK ONE BOX ONLY
- a) Stop smoking before pregnancy? a ☐
- b) Cut down or stop during pregnancy? b ☐
- c) Smoke as usual during pregnancy? c ☐
- d) Don't know d ☐

5. What country were you born in? _____ ☐☐☐

6. How many brothers do or did you have? NUMBER ☐☐
IF 'NONE' GO TO QUESTION 7, IF 'ONE OR MORE':

NUMBER
- 6.1 How many ***older*** brothers? ☐☐
- 6.2 How many ***younger*** brothers? ☐☐
- 6.3 How many of your brothers ever had asthma? ☐☐

6.4 How many of your ***other*** brothers ever had eczema, skin or nasal allergy or hay fever? NUMBER ☐☐

7. How many sisters do or did you have? NUMBER ☐☐
IF 'NONE' GO TO QUESTION 8, IF 'ONE OR MORE':

NUMBER
- 7.1 How many ***older*** sisters? ☐☐
- 7.2 How many ***younger*** sisters? ☐☐
- 7.3 How many of your sisters ever had asthma? ☐☐
- 7.4 How many of your ***other*** sisters ever had eczema, skin or nasal allergy or hay fever? ☐☐

8. Did your mother ***ever*** have asthma? NO ☐ YES ☐ DON'T KNOW ☐

9. Did your mother ***ever*** have eczema, skin or nasal allergy or hay fever? NO ☐ YES ☐ DON'T KNOW ☐

10. Did your father ***ever*** have asthma? NO ☐ YES ☐ DON'T KNOW ☐

	NO	YES	DON'T KNOW
11. Did your father ***ever*** have eczema, skin or nasal allergy or hay fever?	☐	☐	☐
12. Did you regularly share your bedroom with any ***older*** children before the age of five years?	☐	☐	☐
13. Did you go to a school, play-school or nursery with ***older*** children before the age of five years?	☐	☐	☐
14. Did you have a serious respiratory infection before the age of five years?	☐	☐	☐

	NO	YES	DONT KNOW
15. Was there a dog in your home?			
15.1 During your first year of life	☐	☐	☐
15.2 When you were aged 1 to 4 years	☐	☐	☐
15.3 When you were aged 5-15 years	☐	☐	☐

	NO	YES	DONT KNOW
16. Was there a cat in your home?			
16.1. During your first year of life	☐	☐	☐
16.2 When you were aged 1 to 4 years	☐	☐	☐
16.3 When you were aged 5-15 years	☐	☐	☐

17. What term best describes the place you lived most of the time when you were under the age of five years?

	TICK ONE BOX ONLY	
a) Farm	a	☐
b) Village in a rural area	b	☐
c) Small town	c	☐
d) Suburb of a city	d	☐
e) Inner city	e	☐

WORK AND EDUCATION

	NO	YES
18. Are you a full time student?	☐	☐

IF 'YES' GO TO QUESTION 21, IF 'NO':

	YEARS
18.1 At what age did you complete full time education?	☐☐

I would now like to ask you some questions on the type of jobs that you have done.

18.2. Are you currently:	TICK ONE BOX ONLY	
Employed (including military service)	1	☐
Self employed	2	☐
Unemployed, looking for work	3	☐
Not working because of poor health	4	☐
Full-time house-person	5	☐
Full time student	6	☐
Retired	7	☐
Other	8	☐

	NO	YES
18.3 Have you ***ever*** had a job for more than <u>three consecutive months</u>?	☐	☐

IF 'NO' GO TO Q22, IF 'YES':

YEARS

18.4 How old were you when you started your first job? ☐☐

18.5. What was this first job? (*be as precise as possible*) ☐☐☐☐

_____

NO YES

18.6. Would you say that allergies or breathing problems influenced your **initial** job choice? ☐ ☐

NO YES

18.7. Would you say that allergies or breathing problems are likely to influence your **future** job choices? ☐ ☐

NO YES

18.8. Are you currently still working in your first job (as in question 18.4)? ☐ ☐

IF 'YE'S, GO TO Q18.11, IF 'NO':

18.9 What is your current or most recent job? [Be as precise as possible, if not working, please complete as Not Working]

_____ ☐☐☐☐

YEARS

18.10 How old were you when you started working in this job? ☐☐

18.11 In this job were you: TICK ONE BOX ONLY

a) A manager working for an employer? a ☐

b) A foreman or supervisor working for an employer? b ☐

c) Working for an employer, but neither a manager, supervisor or foreman? c ☐

d) Self-employed? d ☐

NO YES

19. Does or did being at work ever make your chest tight or wheezy? ☐ ☐

NO YES

19.1 Is or was your breathing better at weekends or holidays? ☐ ☐

DAYS

20. How many days of work have you lost because of asthma, shortness of breath or wheezing in the last **12 months?** ☐☐☐

NO YES

21. Have you ever worked in a job which exposed you to vapours, gas, dust or fumes? ☐ ☐

IF 'NO' GO TO QUESTION 22, IF 'YES':

21.1 What was or is this job? [Be as precise as possible] I*f current job write 'current job'* ☐☐☐☐

_____

NO YES

22. Have you ever been involved in an incident at home, work or elsewhere that exposed you to high levels of vapours, gases or fumes? ☐ ☐

IF NO GO TO Q23; IF YES:

22.1 When did this happen?

a) Less than a year ago a ☐

b) Between one and five years ago b ☐

c) More than five years ago c ☐

22.2 Could you classify this incident as:

a) A fire or an explosion a ☐

b) A leak or a spill b ☐

c) (Mixing of) cleaning products c ☐

d) Something else:_____ d ☐

22.3 Where did this happen?

a) In your own home — a ☐
b) In your workplace — b ☐
c) Somewhere else indoors — c ☐
d) Outdoors — d ☐

22.4 Did you experience respiratory symptoms within 24 hours following this incident? NO ☐ YES ☐

23. Have you ever had to change or leave your job because it affected your breathing? NO ☐ YES ☐

IF 'NO' GO TO QUESTION 24 IF 'YES':

23.1 What was this job? [Be as precise as possible]

_____ ☐☐☐☐

ENVIRONMENT

24. How often do cars pass your house? TICK ONE BOX ONLY

a) More than 80 per hour — a ☐
b) between 21and 80 per hour — b ☐
c) between 5 and 20 per hour — c ☐
d) less than 5 per hour — d ☐

25. How often do heavy vehicles (e.g. trucks/buses) pass your house? TICK ONE BOX ONLY

a) More than 20 per hour — a ☐
b) between 4 and 20 per hour — b ☐
c) at least one but less than 4 per hour — c ☐
d) less than one per hour — d ☐

TOBACCO AND ALCOHOL

26. Have you ever smoked for as long as a year? NO ☐ YES ☐

['YES' means at least 20 packs of cigarettes or 12 oz (360 grams) of tobacco in a lifetime, or at least one cigarette per day or one cigar a week for one year]

IF 'NO' GO TO QUESTION 27, IF 'YES':

26.1 How old were you when you started smoking? YEARS ☐☐

26.2 Do you **now** smoke, as of ***one month ago***? NO ☐ YES ☐

***IF 'NO' GO TO QUESTION 26.3, IF 'YES'*:**

26.2.1-4 How much do you ***now*** smoke on average NUMBER

26.2.1 number of cigarettes ***per day*** ☐☐
26.2.2 number of cigarillos ***per day*** ☐☐
26.2.3 number of cigars ***a week*** ☐☐
26.2.4 pipe tobacco in a) ounces / ***week*** ☐☐
b) grams / ***week*** ☐☐☐

NO YES

26.3 Have you stopped or cut down smoking? ☐ ☐

IF 'NO' GO TO QUESTION 26.4, IF 'YES':

YEARS

26.3.1 How old were you when you stopped or cut down smoking? ☐☐

26.3.2. 1-4 ***on average*** of the entire time you smoked, before you stopped or cut down, how much did you smoke?

NUMBER

26.3.2.1 number of cigarettes per day ☐☐

26.3.2.2 number of cigarillos per day ☐☐

26.3.2.3 number of cigars a week ☐☐

26.3.2.4 pipe tobacco in a) ounces / week ☐☐

b) grams / week ☐☐☐

NO YES

26.4 Do you or did you inhale the smoke? ☐ ☐

NO YES

27. Have you been **regularly** exposed to tobacco smoke in the last ***12months***? ☐ ☐

['Regularly' means on most days or nights]

IF 'NO' GO TO QUESTION 28, IF 'YES':

NUMBER

27.1 Not counting yourself, how many people in your household smoke regularly? ☐☐

NO YES

27.2 Do people smoke regularly in the room where you work? ☐ ☐

HOURS

27.3 How many hours per day are you exposed to ***other people's*** tobacco smoke? ☐☐

Please provide more information.

27.4 On average how many hours per day, are you exposed to other peoples tobacco smoke In the following locations

NUMBER

a) At home a ☐☐

b) At workplace b ☐☐

c) In bars, restaurants, cinemas or similar social settings c ☐☐

d) Elsewhere d ☐☐

28. How many units of alcohol do you drink daily/weekly?

(one unit = one small bottle of beer (250 ml), a small glass of red or white wine (120 ml) or one shot of spirits (40ml))

TICK ONE BOX ONLY

a) Never a ☐

b) Less than one a week b ☐

c) At least one a week but less than one a day c ☐

d) 1-3 units a day d ☐

e) 4 units a day e ☐

f) More than 5 units per day f ☐

MEDICINES

29. Have you used any **inhaled** (not nasal) medicines to help your breathing at any time in the last ***12 months***? ***IF NO' GO TO QUESTION 30, IF 'YES':*** NO ☐ YES ☐

What have you used in the last ***12 months***?
INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

29.1 **short acting beta-2-agonist inhalers** NO ☐ YES ☐

29.1.1 If used, how many puffs per day have you used **in the last week?** PUFFS ☐☐

29.2 **long acting beta-2-agonist inhalers** NO ☐ YES ☐

29.2.1 If used, how many puffs per day have you used **in the last week?** PUFFS ☐☐

29.2.2 Is this a combination with a steroids? NO ☐ YES ☐
If YES GO TO QUESTION 29.3.2

29.3 **inhaled steroids** **DOSE:_____** NO ☐ YES ☐
(***if combined B2 and steroid please insert inhaled steroid dose***)

29.3.1 If used, how many puffs per day have you used **in the last week?** PUFFS ☐☐

29.3.2 If used, which one? _____ ☐☐☐

29.4 **anti-muscarinic inhalers** NO ☐ YES ☐

29.4.1 If used, how many puffs per day have you used **in the last week?** PUFFS ☐☐

30. Have you used any **pills**, **capsules**, **tablets** or **medicines**, other than inhaled medicines, to help your breathing at any time in the last ***12 months***? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 31, IF 'YES':

What have you used in the last ***12 months***?
INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

30.1 **oral methylxanthines** NO ☐ YES ☐

30.2 **oral steroids** NO ☐ YES ☐
If used, have you used these in the last 12 months
a. More or less continuously ☐
b. More than 2 short courses in the last 12 months ☐
c. More than 1 short course in the last 12 months ☐
d. A single short course in the last 12 months ☐

NO YES

30.3 **oral anti-leukotrienes** ☐ ☐

NO YES

31. **In the last 5 years** have you ever used inhaled steroids? ☐ ☐
IF NO GO TO QUESTION 32

YEARS

31.1. How old were you when you first started to use inhaled steroids? ☐☐

NO YES

31.2. Have you used inhaled steroids ***every year*** in the last 5 years? ☐ ☐
IF NO GO TO QUESTION 31.3, IF YES

MONTHS

31.2.1. On average how many months each year have you taken them? ☐☐
NOW GO TO Q32

YEARS

31.3 How many of the last 5 years have you taken inhaled steroids? ☐☐

MONTHS

31.4. On average how many months of each of these years have you taken them? ☐☐

USE OF HEALTH SERVICES

NO YES DONT KNOW

32. Have you been vaccinated for allergy in the last 5 years? ☐ ☐ ☐
IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 33, IF 'YES':

NO YES

32.1 Have you been vaccinated for allergy in the last ***12 months***? ☐ ☐

NO YES

33. In the last 5 years have you visited a hospital casualty department or emergency room because of breathing problems? ***IF NO GO TO Q34, IF YES*** ☐ ☐

NO YES

33.1. Have you visited a hospital casualty department or emergency room because of breathing problems in the ***last 12 months***? ***IF NO GO TO 34, IF YES*** ☐ ☐

NO YES

33.1.1 Was this due to asthma, shortness of breath or wheezing? ☐ ☐

TIMES

33.1.2 How many times ***in the last 12 months*****?** ☐☐

34 How many nights have you spent in hospital with any of the following conditions in the last 5 years?

NUMBER OF NIGHTS

a) Asthma a ☐☐
b) Chest infection b ☐☐
c) COPD c ☐☐
d) Sinusitis d ☐☐
e) Other e ☐☐

NO YES

34.1 Have you spent a night in hospital in the ***last 12 months***? ☐ ☐

NO YES

35. In the last 5 years have you been seen by a doctor because of breathing problems or because of shortness of breath? ***IF NO GO TO Q36, IF YES*** ☐ ☐

NO YES

35.1 Have you been seen by a general practitioner because of breathing problems or shortness of breath in the ***last 12 months? IF NO GO TO Q35.2, IF YES*** ☐ ☐

NUMBER

35.1.1 How many times? ☐☐

NO YES

35.2. Have you seen a specialist (chest physician, allergy specialist, internal medicine specialist, ENT doctor) because of your breathing problems or shortness of breath ***in the last 12 months***? ☐ ☐

NUMBER

35.4.1 How many times? ☐☐

M F

36. Gender ☐ ☐

DAY MONTH YEAR

37. Date of birth ☐☐ ☐☐ ☐☐

INTERVIEW TYPE? **TICK ONE BOX ONLY**

a) At centre face to face	a	☐
b) At home face to face	b	☐
c) By telephone	c	☐
d) Self completed at home	d	☐
		☐

END FIELDWORKER NUMBER ☐

APPENDIX 2: Euro QOL

Health Questionnaire

English version for the UK

(Validated for Ireland)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility

I have no problems in walking about	❑
I have some problems in walking about	❑
I am confined to bed	❑

Self-Care

I have no problems with self-care	❑
I have some problems washing or dressing myself	❑
I am unable to wash or dress myself	❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities	❑
I have some problems with performing my usual activities	❑
I am unable to perform my usual activities	❑

Pain/Discomfort

I have no pain or discomfort	❑
I have moderate pain or discomfort	❑
I have extreme pain or discomfort	❑

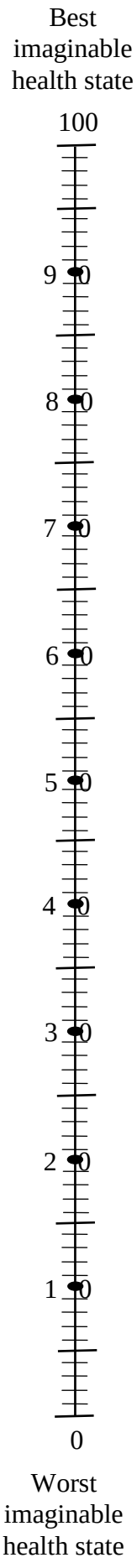
Anxiety/Depression

I am not anxious or depressed	❑
I am moderately anxious or depressed	❑
I am extremely anxious or depressed	❑

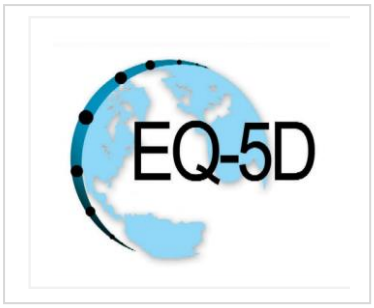
To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



User Guide



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1. Introduction

This guide has been developed in order to give users of EQ-5D basic information on how to use EQ-5D. Topics include administering the instrument, setting up a database for data collected using EQ-5D as well as information about how to present the results. Also included are some frequently asked questions dealing with common issues regarding the use of EQ-5D and a list of currently available EuroQoL products.

EuroQoL Group

- The EuroQoL Group is a network of international multidisciplinary researchers devoted to the measurement of health status. Established in 1987, the EuroQoL Group originally consisted of researchers from Europe, but nowadays includes members from North America, Asia, Africa, Australia, and New Zealand. The Group is responsible for the development of EQ-5D, a preference based measure of health status that is now widely used in clinical trials, observational studies and other health surveys.

- The EuroQoL Group has been holding annual scientific meetings since its inception in 1987.

- The EuroQoL Group can be justifiably proud of its collective scientific achievements over the last 20 years. Research areas include: valuation, EQ-5D use in clinical studies and in population surveys, experimentation with the EQ-5D descriptive system, computerized applications, interpretation of EQ-5D ratings and the role of EQ-5D in measuring social inequalities in self-reported health.

- The EuroQoL Group's website (www.euroqol.org) contains detailed information about EQ-5D, guidance for users, a list of available language versions, EQ-5D references and contact details.

EQ-5D

EQ-5D is a standardised measure of health status developed by the EuroQoL Group in order to provide a simple, generic measure of health for clinical and economic appraisal[1]. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status that can be used in the clinical and economic evaluation of health care as well as in population health surveys (Figure 1).

EQ-5D is designed for self-completion by respondents and is ideally suited for use in postal surveys, in clinics, and in face-to-face interviews. It is cognitively undemanding, taking only a few minutes to complete. Instructions to respondents are included in the questionnaire.

EQ-5D essentially consists of 2 pages - the EQ-5D descriptive system (page 2) and the EQ visual analogue scale (EQ VAS) (page 3). The EQ-5D descriptive system comprises the following 5 dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no problems, some problems, severe problems. The respondent is asked to indicate his/her health state by ticking (or placing a cross) in the box against the most appropriate statement in each of the 5 dimensions. This decision results in a 1-digit number expressing the level selected for that dimension. The digits for 5 dimensions can be combined in a 5-digit number describing the respondent's health state. **It should be noted that the numerals 1-3 have no arithmetic properties and should not be used as a cardinal score.** This current 3-level, 5-dimensional format of EQ-5D will remain unchanged for the immediate future. However a EuroQoL task force is developing a 5-level version. This should become available around 2009.

The EQ VAS records the respondent's self-rated health on a vertical, visual analogue scale where the endpoints are labelled 'Best imaginable health state' and 'Worst imaginable health state'. This information can be used as a quantitative measure of health outcome as judged by the individual respondents.

[1] EuroQoL Group. EuroQoL-a new facility for the measurement of health-related quality of life. Health Policy 1990;16:199-208

Figure 1: EQ-5D (UK English version)

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

Mobility
I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care
I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*
I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

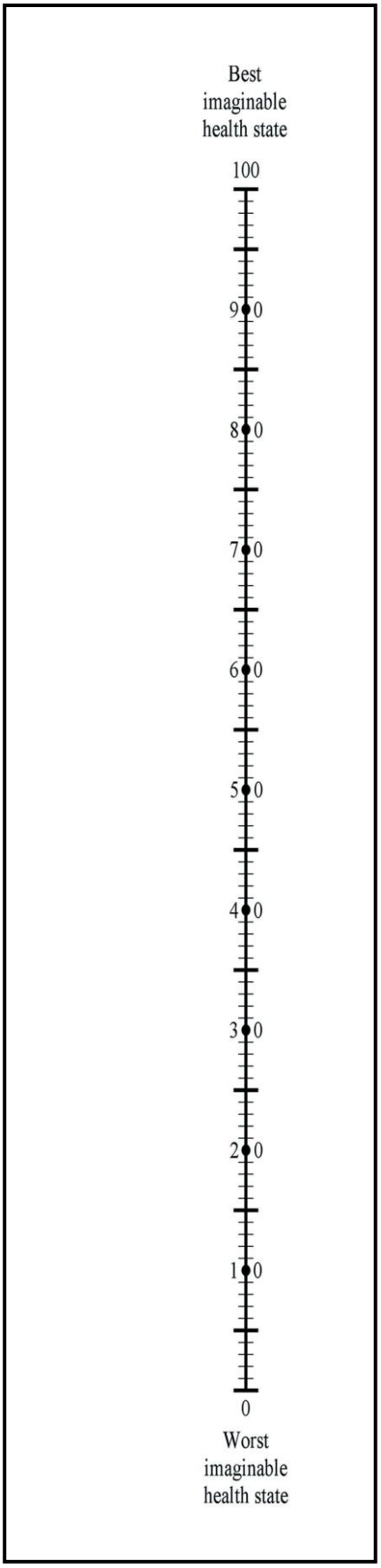
Pain/Discomfort
I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety/Depression
I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

5

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.



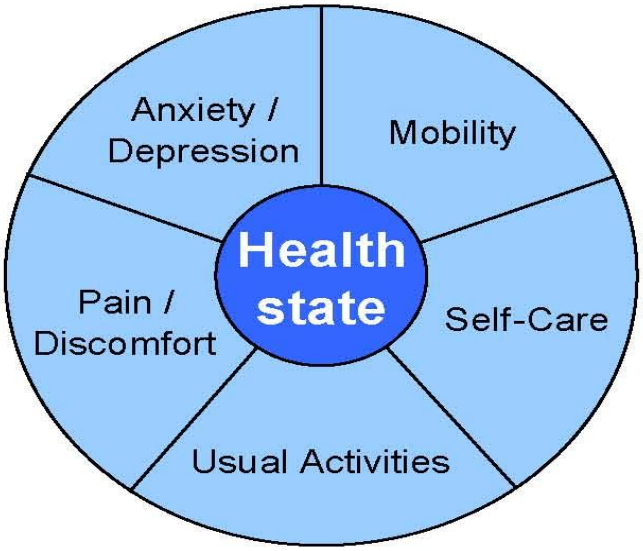
Your own health state today

What is a health state?

Each of the 5 dimensions comprising the EQ-5D descriptive system is divided into 3 levels of perceived problems:

Level 1: indicating no problem
Level 2: indicating some problems
Level 3: indicating extreme problems

A unique health state is defined by combining 1 level from each of the 5 dimensions.



A total of 243 possible health states is defined in this way. Each state is referred to in terms of a 5 digit code. For example, state 11111 indicates no problems on any of the 5 dimensions, while state 11223 indicates no problems with mobility and self care, some problems with performing usual activities, moderate pain or discomfort and extreme anxiety or depression.

Note: Two further states (unconscious and death) are included in the full set of 245 EQ-5D health states, but information on these states is not collected via self-report.

Versions of EQ-5D

EQ-5D in different languages

Currently there are more than 100 translated versions of EQ-5D. If you want to know if there is an EQ-5D version appropriate for your country, please consult the website.

All translations/adaptations of EQ-5D are produced using a standardised translation protocol that conforms to internationally recognized guidelines. These guidelines aim to ensure semantic and conceptual equivalence and involve a forward/backward translation process and lay panel assessment. Only the EuroQoL Group Executive Office can give permission for a translation to be performed and translations can only be stamped as official if they are performed in cooperation with EuroQoL Group reviewers.

Alternative modes of administration

EQ-5D was primarily designed for self-completion by the patient or respondent. However the Group has brief guidelines for the following alternative modes of administration:

(i) Face-to-face
(ii) Self-completion in the presence of an interviewer
(iii) Telephone interview
(iv) Proxy (asking the proxy to rate how he or she, (i.e. the proxy), would rate the subject's health)

Guidelines for telephone and proxy use are available in a number of different languages.

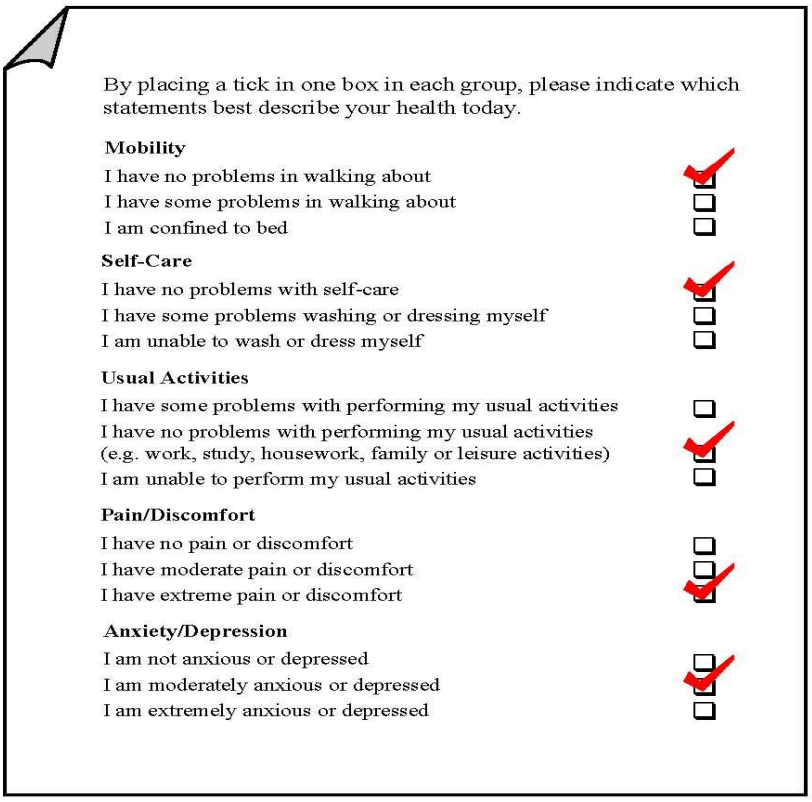
Child versions

EQ-5D is generally considered suitable for children aged 12 years and over (although this may vary in different countries). Currently a EuroQoL Group task force is developing a version for children between 7 and 12 years in international English. This version is being validated in Swedish, Italian, Spanish and German and these versions should become available in 2008.

Please check the EuroQoL website for up-to-date information on the availability of EuroQoL products.

2. Scoring the EQ-5D descriptive system

The EQ-5D descriptive system should be scored as follows:



By placing a tick in one box in each group, please indicate which statements best describe your health today.

Mobility
- I have no problems in walking about ☑
- I have some problems in walking about ☐
- I am confined to bed ☐

Self-Care
- I have no problems with self-care ☑
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

Usual Activities
- I have some problems with performing my usual activities ☐
- I have no problems with performing my usual activities (e.g. work, study, housework, family or leisure activities) ☑
- I am unable to perform my usual activities ☐

Pain/Discomfort
- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☑

Anxiety/Depression
- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☑
- I am extremely anxious or depressed ☐

Levels of perceived problems are coded as follows:

☑ ☐ ☐ Level 1 is coded as a '1'

☐ ☑ ☐ Level 2 is coded as a '2'

☐ ☐ ☑ Level 3 is coded as a '3'

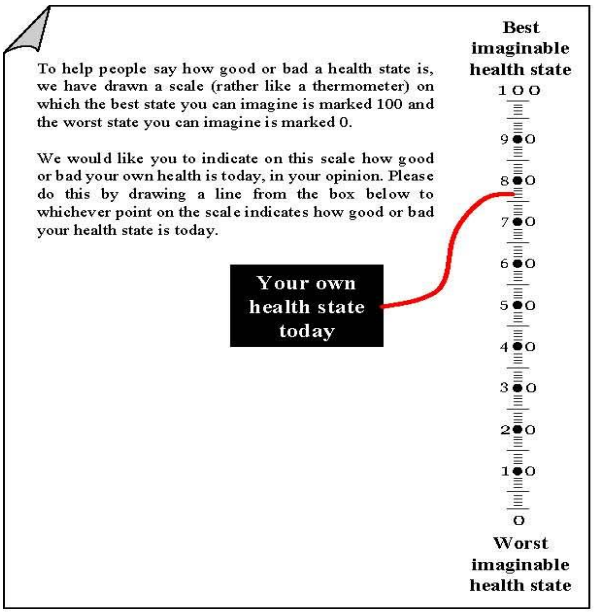
NB: There should be only <u>one</u> response for each dimension.

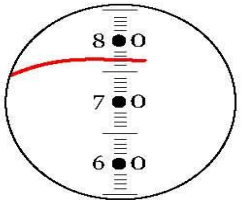
This example identifies the state 11232.

Missing values can be coded as '9'.
Ambiguous values (e.g. 2 boxes are ticked for a single dimension) should be treated as missing values.

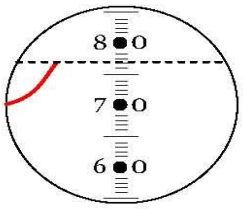
3. Scoring the EQ VAS

The EQ VAS should be scored as follows:


To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.
We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.
Your own health state today
Best imaginable health state
100
90
80
70
60
50
40
30
20
10
0
Worst imaginable health state



For example this response should be coded as 77



Even though the line does not cross the VAS this response can still be scored by drawing a horizontal line from the end point of the response to the VAS. In this example the response should be coded as 77

Missing values should be coded as '999'.

Ambiguous values (e.g. the line crosses the VAS twice) should be treated as missing values.

4. Converting EQ-5D states to a single summary index

EQ-5D health states, defined by the EQ-5D descriptive system, may be converted into a single summary index by applying a formula that essentially attaches values (also called weights) to each of the levels in each dimension. The index can be calculated by deducting the appropriate weights from 1, the value for full health (i.e. state 11111). Information in this format is useful, for example, in cost utility analysis.

Value sets have been derived for EQ-5D in several countries using the EQ-5D visual analogue scale (EQ-5D VAS) valuation technique or the time trade-off (TTO) valuation technique. The list of currently available value sets with the number of respondents and valuation technique applied is presented in table 1. Most of the EQ-5D value sets have been obtained using a representative sample of the general population, thereby ensuring that they represent the societal perspective. For anyone working with EQ-5D data, an essential guide to the Group's available value sets can be found in: EuroQoL Group Monograph series: Volume 2: EQ-5D value sets: inventory, comparative review and user guide, recently published by Springer (see section 8 for more information).

Table 1: List of available value sets as of May 2007

Country	N	Valuation method
Belgium	548	EQ-5D VAS
Denmark	1179	EQ-5D VAS
Denmark	1332	TTO
Europe	6870	EQ-5D VAS
Finland	928	EQ-5D VAS
Germany	339	EQ-5D VAS
Germany	339	TTO
Japan	543	TTO
New Zealand	919	EQ-5D VAS
Netherlands	298	TTO
Slovenia	370	EQ-5D VAS
Spain	294	EQ-5D VAS
Spain	975	TTO
UK	3395	EQ-5D VAS
UK	3395	TTO
US	3773	TTO
Zimbabwe	2384	TTO

Documents containing the scoring algorithms, information on the valuation studies, tables of values for all 243 health states and SPSS and SAS syntax files can be ordered from the EuroQoL Executive Office (userinformationservice@euroqol.org).

5. Organising EQ-5D data

Data collected using EQ-5D can be entered in a database according to the following schema:

Variable name	ID	COUNTRY	YEAR	MOBILITY	SELFCARE	ACTIVITY	PAIN	ANXIETY
Variable description	patient ID number			1=No Problems, 2=Some problems, 3=Extreme problems, 9=Missing value	1=No Problems, 2=Some problems, 3=Extreme problems, 9=Missing value	1=No Problems, 2=Some problems, 3=Extreme problems, 9=Missing value	1=No Problems, 2=Some problems, 3=Extreme problems, 9=Missing value	1=No Problems, 2=Some problems, 3=Extreme problems, 9=Missing value
Data row 1	1001	UK	2006	2	1	2	2	1
Data row 2	1002	UK	2006	1	1	1	1	1

Variable name	STATE	EQ_VAS	SEX	AGE	EDU	METHOD	SOC_ECON
Variable description		999= Missing value	1=male, 2=female, 9=Missing value	999= Missing value	1=low, 2=medium, 3=high, 9=Missing value	0=postal, 1=interview, 2=telephone, 9=Missing value	1=employed, 2=retired, ……, 9=Missing value
Data row 1	21221	80	1	43	1	0	1
Data row 2	21111	90	2	24	2	0	4

NB: The variable names are just examples. However, the variables for the 5 dimensions of the EQ-5D descriptive system should be named 'mobility', 'selfcare', 'activity', 'pain', and 'anxiety'. If they are given different names the syntax codes containing the value sets that are distributed by the EuroQoL Group will not work properly.

6. Presenting EQ-5D results

Data collected using EQ-5D can be presented in various ways. A basic subdivision can be made according to the structure of the EQ-5D:

1. Presenting results from the descriptive system as a health profile
2. Presenting results of the EQ VAS as a measure of overall self-rated health status
3. Presenting results from the descriptive system as a weighted index

However, the way results are presented is partly determined by what message you, as a researcher, wish to convey to your audience.

Health profiles

One way of presenting data as a health profile is by making a table with the frequency or the proportion of reported problems for each level for each dimension. These tables can be broken down to include the proportions per subgroup, such as age, before vs. after treatment, treatment vs. comparator, etc.

Sometimes it is more convenient to dichotomise the EQ-5D levels into 'no problems' (i.e. level 1) and 'problems' (i.e. levels 2 and 3), thereby changing the profile into frequencies of reported problems. This can be the case, for example, in a general population survey where the numbers of reported level 3 problems are very low. Tables 2 and 3 are examples of how to present EQ-5D data in tabulated form. The data for the tables originates from a general population survey in the UK[2].

[2]Kind P, Dolan P, Gudex C, Williams A. Variations in population health status: results from a United Kingdom national questionnaire survey Bmj 1998;316 (7133): 736-41.

Table 2: Proportion of levels 1, 2 and 3 by dimension and by age group

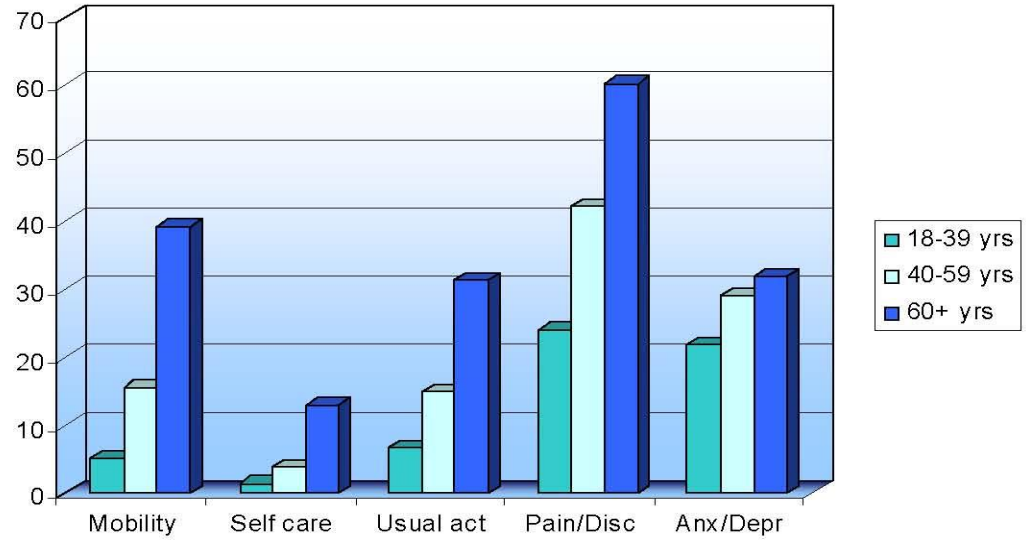
EQ-5D DIMENSION		AGE GROUPS 18-29	30-39	40-49	50-59	60-69	70-79	80+	TOTAL
MOBILITY	Level 1	95.4	92.2	89.7	78.1	70.7	60.2	43.3	81.6
	Level 2	4.6	7.6	9.9	21.9	29.3	39.8	56.7	18.3
	Level 3	0.0	0.1	0.4	0.0	0.0	0.0	0.0	0.1
SELF-CARE	Level 1	99.1	98.4	95.8	94.8	94.3	92.6	83.7	95.7
	Level 2	0.9	1.5	4.0	5.2	5.5	7.1	15.6	4.1
	Level 3	0.0	0.1	0.2	0.0	0.2	0.2	0.7	0.1
USUAL ACTIVITIES	Level 1	93.3	91.4	89.2	78.1	75.3	73.7	56.0	83.7
	Level 2	6.3	7.9	9.4	18.8	21.6	22.1	38.3	14.2
	Level 3	0.4	0.7	1.5	3.0	3.1	4.2	5.7	2.1
PAIN / DISCOMFORT	Level 1	83.9	80.7	74.1	56.3	53.8	44.0	39.7	67.0
	Level 2	15.8	17.7	22.8	38.1	40.6	48.4	49.6	29.2
	Level 3	0.3	1.6	3.1	5.6	5.6	7.6	10.6	3.8
ANXIETY / DEPRESSION	Level 1	86.5	82.6	81.3	72.8	72.0	74.7	75.2	79.1
	Level 2	12.6	16.4	16.9	24.4	25.1	22.6	24.1	19.1
	Level 3	0.9	1.0	1.8	2.8	2.9	2.7	0.7	1.8

Table 3: Frequency of reported problems by dimension and age group

EQ-5D DIMENSION		AGE GROUPS 18-29	30-39	40-49	50-59	60-69	70-79	80+	TOTAL
MOBILITY	No problems	643	631	489	362	339	246	61	2770
	Problems	31	53	56	101	140	162	81	625
SELF-CARE	No problems	668	673	522	439	452	378	119	3251
	Problems	6	11	23	24	27	30	23	144
USUAL ACTIVITIES	No problems	629	625	486	362	361	301	80	2842
	Problems	45	59	59	101	118	107	62	553
PAIN / DISCOMFORT	No problems	566	552	404	261	258	179	56	2275
	Problems	108	132	141	202	221	229	86	1120
ANXIETY / DEPRESSION	No problems	583	565	443	337	345	305	107	2684
	Problems	91	119	102	126	134	103	35	711

In addition to presenting the results in tabulated form, you can also use graphical presentations. Two or 3 dimensional bar charts can be used to summarise the results in 1 graph, (see figure 2). Figure 2 shows the sum of the proportion of reported level 2 and level 3 problems for each of the 5 EQ-5D dimensions for 3 distinct age groups. Older people reported more problems on all dimensions but the effect of age was strongest for mobility and weakest for anxiety/depression.

Figure 2: Profile of the population (% reporting problem)



EQ VAS

In order to present all aspects of the EQ VAS data, you should present both a measure of the central tendency and a measure of dispersion. This could be the mean values and the standard deviation or, if the data is skewed, the median values and the 25th and 75th percentiles. An example is presented in table 4. The data for the table originates from a general population survey in the UK[3].

Table 4: EQ VAS values by age – mean + standard deviation and median + percentiles

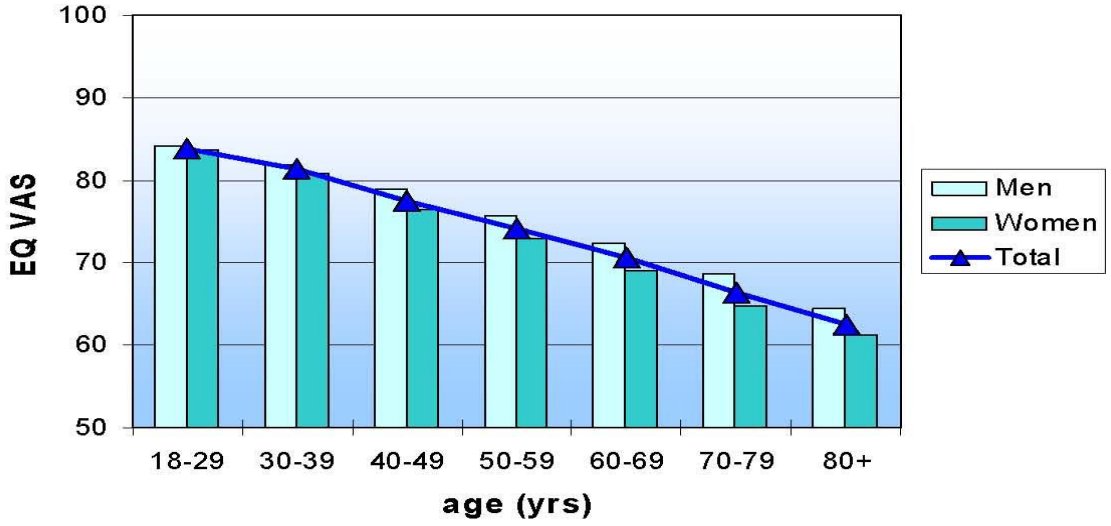
	AGE GROUPS							
EQ VAS	*18-29*	*30-39*	*40-49*	*50-59*	*60-69*	*70-79*	*80+*	*TOTAL*
Mean	87.0	86.2	85.1	81.3	79.8	75.3	72.5	82.8
- Std dev	13.8	14.6	15.5	46.8	17.5	18.5	18.2	23.1
Median	90	90	90	86	85	80	75	90
- 25th	80	80	80	70	70	65	60	75
- 75th	98	95	95	95	93	90	88	95

You can present a graphical representation of the data by using bar charts, line charts, or both (see figure 3). Figure 3 shows the mean EQ VAS ratings reported by

[3] Kind P, Dolan P, Gudex C, Williams A. Variations in population health status: results from a United Kingdom national questionnaire survey Bmj 1998;316 (7133): 736-41.

men, women and both for 7 distinct age groups. The mean EQ VAS ratings are seen to decrease with increasing age. Also, men of all age groups reported higher EQ VAS ratings than women.

Figure 3: Mean population EQ VAS ratings by age group and sex



EQ-5D index

Information about the EQ-5D index can be presented in much the same way as the EQ VAS data. This means that for the index, you can present both a measure of the central tendency and a measure of dispersion. This could be the mean values and the standard deviation (or standard error). If the data is skewed, the median values and the 25th and 75th percentiles could be presented. Tables 5 and 6 and figures 4 and 5 contain 2 examples of how to present EQ-5D index results. Table 5 and figure 4 present the results from a study where the effect of a treatment on health status is investigated. Table 6 and figure 5 show results for a patient population and 3 subgroups (the tables and figures are based on hypothetical data and for illustration purposes only).

Table 5: EQ-5D index values before and after treatment – mean + standard deviation and median + percentiles

EQ-5D index	before treatment	after treatment
Mean	0.59	0.76
- Std error	0.012	0.015
Median	0.60	0.70
- 25th	0.50	0.65
- 75th	0.70	0.80
N	120	110

Figure 4: EQ-5D index values before and after treatment — mean values and 95% confidence intervals

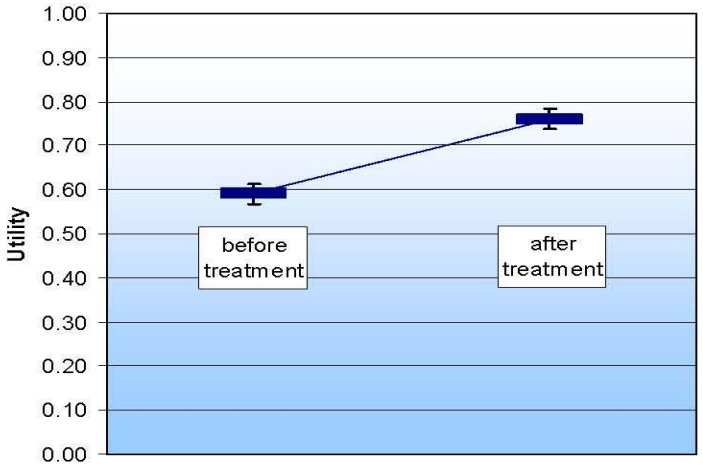
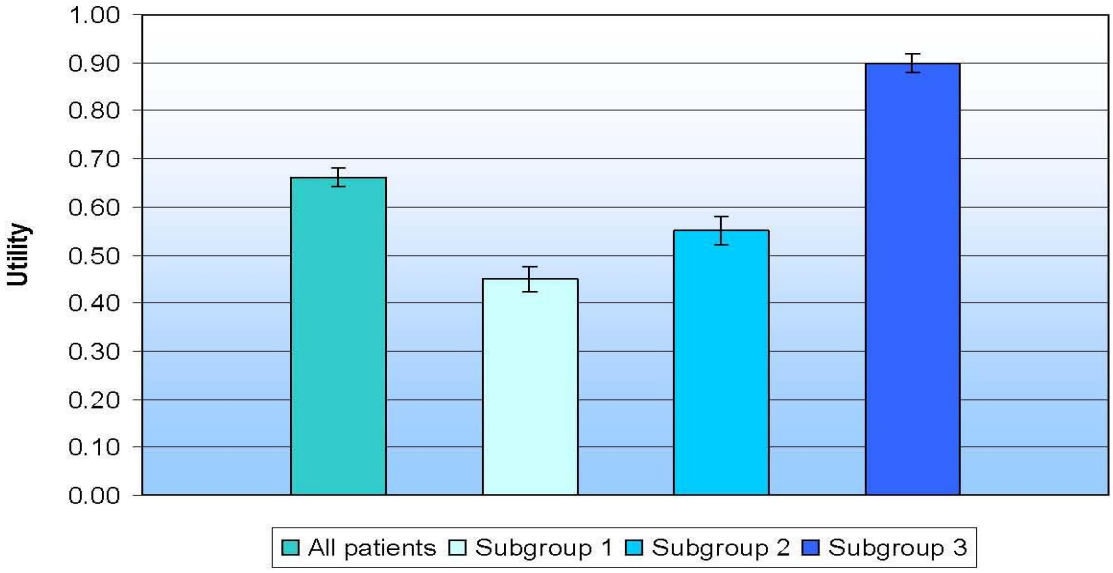


Table 6: EQ-5D index values of the total patient population and the 3 subgroups – mean + standard deviation and median + percentiles

EQ-5D-index	All patients	Subgroup 1	Subgroup 2	Subgroup 3
Mean	0.66	0.45	0.55	0.90
- Std error	0.010	0.013	0.015	0.010
Median	0.55	0.40	0.55	0.95
- 25th	0.50	0.30	0.50	0.80
- 75th	0.70	0.50	0.60	1.00
N	300	100	75	125

Figure 5: EQ-5D index values of the total patient population and the 3 subgroups – mean values and 95% confidence intervals



7. EQ-5D: Frequently asked questions

For what period of time does EQ-5D record health status?

Self-reported health status captured by EQ-5D relates to the respondent's situation at the time of completion. No attempt is made to summarise the recalled health status over the preceding days or weeks, although EQ-5D has been tested in recall mode. An early decision taken by the EuroQoL Group determined that health status measurement ought to apply to the respondent's immediate situation - hence the focus on 'your own health state today'.

General population value sets vs patient population value sets

If you want to undertake a utility analysis you will need to use a value set. Generally speaking utility analysis requires a general population-based value set (as opposed to a patient-based set). The rationale behind this is that the values are supposed to reflect the preferences of local taxpayers and potential receivers of healthcare. Additionally, patients tend to rate their health states higher than the general population because of coping etc, often underestimating their need for healthcare. The EQ-5D value sets are therefore based on the values of the general population.

Difference between the EQ-5D descriptive system and the EQ VAS

The descriptive system can be represented as a health state, e.g. health state 11212 represents a patient who indicates some problems on the usual activities and anxiety/depression dimensions. These health states can be converted to a single index value using (one of) the available EQ-5D value sets. These value sets have been derived using VAS or TTO valuation techniques, and reflect the opinion of the general population. The EQ VAS scores are patient-based and are therefore not representative of the general population. The EQ VAS self-rating records the respondent's own assessment of their health status. The EQ VAS scores however are anchored on 100 = best imaginable health and 0 = worst imaginable health, whereas the value sets are anchored on 11111 = 1 and dead = 0 and can therefore be used in QALY calculations.

Difference between the VAS and TTO techniques

The difference between the value sets based on TTO and those based on VAS is that the techniques used for the elicitation of the values on which the models are based differ. In the TTO task, respondents are asked, for example, to imagine they live in a health state (e.g. 22222) for 10 years and then asked to specify the amount of time they are willing to give up to live in full health instead (i.e. 11111). For example, someone might find 8 years in 11111 equivalent to 10 years in 22222. The VAS technique on the other hand, asks people to indicate where, on a vertical thermometer-like scale ranging from best imaginable health to worst imaginable health, they think a health state should be positioned.

Multinational clinical trials

Information relating to EQ-5D health states gathered in the context of multinational trials may be converted into a single summary index using one of the available EQ-5D value sets. There are different options available to do this using appropriate value sets-however the choice depends on the context in which the information will be used by researchers or decision makers. In cases where data from an international trial are to be used to inform decision makers in a specific country, it seems reasonable to expect decision makers to be interested primarily in value sets that reflect the values for EQ-5D health states in that specific country. So for example, if applications for reimbursement of a drug are rolled out from country to country, country-specific value sets should be applied and reported in each pharmaco-economic report. This is no different from the requirement to use country-specific costs. In the absence of a country-specific value set, the researcher should select another set of values for a population that most closely approximates that country. Sometimes however, information about utilities is required to inform researchers or decision makers in an international context. In these instances, 1 value set applied over all EQ-5D health states data is probably more appropriate.

The decision about which value set to use will also depend on whether the relevant decision making body in each country specifies any requirements or preferences in regard to the methodology used in different contexts (e.g. TTO, standard gamble (SG), VAS or discrete choice modelling (DCM)). These guidelines are the topic of an international ongoing debate but the EuroQoL website is planning to provide a summary of health care decision-making bodies internationally, and their stated requirements regarding the valuation of health states.

Detailed information regarding the valuation protocols, guidelines on which value set to use and tables of all available value sets has recently been published by Springer in: EuroQoL Group Monograph series: Volume 2: EQ-5D value sets: inventory, comparative review and user guide' (see section 8 for more information). Chapter 4 by Nancy Devlin and David Parkin will be of special interest to researchers pondering the issue of which value set to use.

8. Additional information

Key EuroQol references

1. The EuroQol Group (1990). EuroQol-a new facility for the measurement of health-related quality of life. Health Policy 16(3):199-208.

2. Brooks R (1996). EuroQol: the current state of play. Health Policy 37(1):53-72.

3. Dolan P (1997). Modeling valuations for EuroQol health states. Med Care 35(11):1095-108.

4. Roset M, Badia X, Mayo NE (1999). Sample size calculations in studies using the EuroQol 5D. Qual Life Res 8(6):539-49.

5. Greiner W, Weijnen T, Nieuwenhuizen M, et al. (2003). A single European currency for EQ-5D health states. Results from a six country study. Eur J Health Econ; 4(3):222-231.

6. Shaw JW, Johnson JA, Coons SJ (2005). US valuation of the EQ-5D health states: development and testing of the D1 valuation model. Med Care; 43(3): 203-220.

Referring to the EQ-5D instrument in publications

When publishing results obtained with the EQ-5D, the following references can be used:

1. The EuroQol Group (1990). EuroQol-a new facility for the measurement of health-related quality of life. Health Policy 16(3):199-208.

2. Brooks R (1996). EuroQol: the current state of play. Health Policy 37(1):53-72.

If you used a value set in your study you can also include a reference to the publication regarding that value set. The appropriate references for the value sets can be found in the EQ-5D Value Sets Monograph and in the value set summary documents that can be ordered from the EuroQoL Executive Office.

Products available from the EuroQoL Executive Office

EQ-5D language versions/guidelines for different modes of administration

All language versions and guidelines for different modes of administration must be obtained exclusively from the EuroQoL Executive Office. Normally only the language(s) appropriate to the country where the research request originates will be supplied. They are distributed freely provided the research is not being funded by a commercial organization (e.g. a pharmaceutical or medical device company). In these latter instances, sponsorship is requested.

The Measurement and valuation of health status using EQ-5D: A European perspective. Eds Brooks R, Rabin R, de Charro F. Kluwer Acacemic Publishers, 2005

This book reports on the results of the European Union-funded EQ-net project which furthered the development of EQ-5D in the key areas of valuation, application and translation. The book can be obtained from Springer at www.springeronline.com at a cost of €107.95.

Measuring self-reported population health: An international perspective based on EQ-5D. Eds Szende A, Williams A. EuroQoL Group Monographs Volume 1. SpringMed publishing, 2004.

This booklet provides population reference data for a number of different countries and is available on request from the EuroQoL Executive Office.

EQ-5D concepts and methods: a developmental history. Eds Kind P, Brooks R, Rabin R. Springer, 2005.

This book is a collection of papers representing the collective intellectual enterprise of the EuroQoL Group and can be obtained from Springer at www.springeronline.com at a cost of € 85.00.

EQ-5D value sets: Inventory, comparative review and user guide. Eds. Szende A, Oppe M, Devlin N. EuroQoL Group Monographs Volume 2. Springer, 2006.

This book provides an essential guide to the use of the EuroQoL Group's value sets for anyone working with EQ-5D data and can be obtained from Springer at www.springeronline.com at a cost of € 49.95.

Future developments

Since 2002, the EuroQoL Foundation has provided modest funding for EuroQoL members to carry out innovative EQ-5D-related research. Since 2004, the Group has been establishing specific task forces to:

- Investigate the use of EQ-5D in different disease areas
- Develop a 5-level version of EQ-5D
- Explore different valuation methodologies for the 5-level version
- Develop an EQ-5D version for children aged 7-12 years in different languages
- Investigate the use of EQ-5D in population health

- Explore the use of electronic versions of EQ-5D in pc and web-based applications as well as palm pilots and (in the future) cell phones. This task force will also investigate the eliciting of values via the computer

Contact information:

For more information please look at the EuroQoL website at www.euroqol.org or e-mail us at userinformationservice@euroqol.org

Acknowledgements:

Part of this user guide was taken from and is based on the UK user guide that was developed by Professor Paul Kind from York University, UK in 1998.

Appendix 3 - Results sheet

Subject ID
Gender
Age

Mark the answer given by participant with a light colour marker.

Smell test

1	Orange	Blackberry	Strawberry	Pineapple
2	Smoke	Glue	Leather	Grass
3	Honey	Vanilla	Chocolate	Cinnamon
4	Chive	Peppermint	Fir	Onion
5	Coconut	Banana	Walnut	Cherry
6	Peach	Apple	Lemon	Grapefruit
7	Liquorice	Gum	Spearmint	Cookies
8	Cigarette	Coffee	Wine	Smoke
9	Cloves	Pepper	Cinnamon	Mustard
10	Pear	Plum	Peach	Pineapple
11	Camomille	Raspberry	Rose	Cherry
12	Bread	Fish	Cheese	Ham

SCORE (sum the number of correct identifications)

PNIF

1ST Sniff	l/min
2nd Sniff	l/min
3RD Sniff	l/min

HEIGHT AND WEIGHT – ENTER HERE AND INTO EASYONE SPIROMETER AS PROMPTED

Height — Metres .

Weight — Kilograms

Hip Circumference 1st Measurement . cm

Hip Circumference 2nd Measurement . cm

Waist Circumference 1st Measurement . cm

Waist Circumference 2nd Measurement . cm

No Yes
Spirometry outcome

Test completed

Day Month Year

Date of spirometry if different from Questionnaire date Date

Skin Prick Allergy tests

Are you currently taking any oral antihistamine medication (tablets or syrup)? No ☐ Yes ☐

Skin test outcome *Test completed* No ☐ Yes ☐

Mark top and bottom

Tim grass	Grass Mix
D pter	Cat
Birch	Blattella
Olive	Alternaria
Dog	Artemisia
Parietaria	D farinae
+ve	-ve

Tim Grass ☐☐ 1st diam ☐☐ 2nd diam

Grass Mix ☐☐ 1st diam ☐☐ 2nd diam

D Pter ☐☐ 1st diam ☐☐ 2nd diam

Cat ☐☐ 1st diam ☐☐ 2nd diam

Birch ☐☐ 1st diam ☐☐ 2nd diam

Blattella ☐☐ 1st diam ☐☐ 2nd diam

Olive ☐☐ 1st diam ☐☐ 2nd diam

Alternaria ☐☐ 1st diam ☐☐ 2nd diam

Dog ☐☐ 1st diam ☐☐ 2nd diam

Artemisia ☐☐ 1st diam ☐☐ 2nd diam

Parietaria ☐☐ 1st diam ☐☐ 2nd diam

D farine ☐☐ 1st diam ☐☐ 2nd diam

+ve ☐☐ 1st diam ☐☐ 2nd diam

-ve ☐☐ 1st diam ☐☐ 2nd diam

Bloods

Blood samples *Samples collected?* No ☐ Yes ☐

Enter the number of each type of blood bottle obtained

Serum separator tubes ☐ Aliquots ☐ Barcode sticker……..

EDTA tubes ☐

Appendix 4 - Skin Prick Test template

Tim Grass	Grass Mix
Der pter	Cat
Birch	Blattella
Olive	Alternaria
Dog	Artemisia
Parietaria	Der farinae
+ve	-ve

Appendix 5 - Inhaled steroid dose table

Estimated Equivalent Doses for Inhaled Steroids for use in Questionnaire II Question 8.

Drug or Drug & propellant type	Total dose in μg per day		
	Low	**Medium**	**High**
Beclomethasone CFC	<500	500-1000	>1000
Beclomethasone HFA	<250	250-500	>500
Budesonide DPI	<600	600-1000	>1000
Fluticasone	<250	250-500	>500
Mometasone	<400	400-800	>800
Triamcinalone	<1000	1000-2000	>2000
Flunisolide	<1000	1000-2000	>2000

Appendix 6

Participant Invitation Letter

Imperial College London
Respiratory Epidemiology & Public Health
National Heart and Lung Institute
RBH Campus
Emmanuel Kaye Building
Manresa Road
London SW3 6LR

Tel: 44 207-3528121 extn 3506
Fax: 44 2073518322

Head of Unit
Professor Peter Burney
MA MD FRCP FFPH FMedSci
Email:p.burney@imperial.ac.uk

Ethics Ref: 08/H0718-33

Dear …….

Re**: GA2LEN Survey Follow-Up Study - Participant Invitation Letter**

Thank you for agreeing to consider taking part in the **GA2LEN Survey Follow-Up Study.**

As we discussed with you on the phone we are now sending you:

1) The Participant Information Sheet which describes the study to you. You can chose to take part in all, some or none of the steps.
2) The Food Frequency Questionnaire which we would like you to complete and bring with you to the testing centre. This questionnaire may take up to twenty minutes to fill in. Please still come to the testing centre even if you have not found the time to complete it.
3) An appointment time for you to come to the testing centre
4) A map of how to find us.

Please contact **Miss Mun Lim, who is coordinating this study, on telephone number 020-73528121 ext 3503 email: m.lim@imperial.ac.uk if you have any queries or concerns.**

We look forward to seeing you at the clinic shortly.

If you do not wish to take part in this research any more please contact Miss Mun Lim (contact details above). Even if you do not wish to come to the clinic please consider completing the food frequency questionnaire and returning it to us.

Thank you.

Yours sincerely,

Professor Peter Burney
Professor of Respiratory Epidemiology & Public Health
Imperial College London

Dr Nada Lemic
Consultant in Public Health
Bromley Primary Care Trust

Imperial College London

GA²LEN Global Allergy and Asthma European Network
Network of Excellence

Imperial College London
Respiratory Epidemiology & Public Health
National Heart and Lung Institute
RBH Campus
Emmanuel Kaye Building
Manresa Road
London SW3 6LR

Tel: 44 207-3528121 extn 3506
Fax: 44 2073518322

Head of Unit
Professor Peter Burney
MA MD FRCP FFPH FMedSci
Email:p.burney@imperial.ac.uk

Ethics Ref: 08/H0718-33

Dear……

Re: GA²LEN Survey Follow-Up Study - Participant Invitation Letter

Recently, as part of a survey on allergies and asthma in Bromley you completed a short questionnaire and returned it to us. On this questionnaire you indicated that you may be willing to take part in further research.

We are writing to invite you to take part in the GA²LEN Follow-Up Study. This study is part of an international research programme to investigate the causes of asthma and allergies. Even if you have no asthma and no allergies you can still make a valuable contribution to this research.

Enclosed with this letter is a Participant Information Sheet that describes what is involved in the survey. You may chose to take part in all, some or none of the steps involved.

Please read the Participant Information Sheet to help you decide whether you wish to take part.

You can request further details and or let us know your decision by
a) contacting **Miss Mun Lim, who is coordinating this study, on telephone number 020-73528121 ext 3503 email: m.lim@imperial.ac.uk or**
b) **complete the attached reply slip and return it in the reply paid envelope.**

This survey will be taking place in 17 towns in different countries across Europe. It is funded by the European Commission and Imperial College London is coordinating the study, in collaboration with Bromley Primary Care Trust. This study has been approved by the NHS Research Ethics Committee.

Please read carefully the attached **Participant Information Sheet**.

Thank you.

Yours sincerely,

Professor Peter Burney
Professor of Respiratory Epidemiology & Public Health
Imperial College London

Dr Nada Lemic
Consultant in Public Health
Bromley Primary Care Trust

Imperial College
London

Bromley NHS
Primary Care Trust

GA²LEN
Global Allergy and Asthma European Network
Network of Excellence

Global Allergy and Asthma European Network (GA²LEN)

Survey Follow-Up Study

Reply Slip

Please tick the appropriate box below.

I would like to take part in the GA²LEN Survey Follow-Up Study.

Yes	
No	
I would like to find out more about this study before I decide. Please can you phone me	

Please give your preferred contact details:

Day Time telephone no (8am-5pm) ……..

Evening telephone no (5pm-6pm) ……..

Mobile Telephone no ……

Email address ……

We will contact you as soon as possible to make further arrangements.

Please return this slip together in the pre-paid envelope.

Thank You for your time.

If you have any queries, please contact Ms Mun Lim at 020-73528121 ext 3503

Appendix 7
Participant Information Sheet

Imperial College London
Respiratory Epidemiology & Public Health
National Heart and Lung Institute
RBH Campus
Emmanuel Kaye Building
Manresa Road
London SW3 6LR

Tel: 44 207-3528121 extn 3506
Fax: 44 2073518322

Head of Unit
Professor Peter Burney
MA MD FRCP FFPH FMedSci
Email:p.burney@imperial.ac.uk

Ethics Committee Ref: 08/H0718-33

Participant Information Sheet

Global Allergy and Asthma European Network of Excellence
Survey Follow Up Study

Introduction

We are inviting you to take part in the GA²LEN Follow-Up Study. This study is part of an international research programme to investigate the causes of asthma and allergies. Even if you have no asthma and no allergies you can still make a valuable contribution to this research.

What is the purpose of the study?

This study will measure the burden of allergic disease across Europe and investigate the causes of asthma and allergies. In particular we want to investigate:

1) What proportion of people are allergic to substances produced by a common bacteria (staphylococcus aureus); that is present in the environment; and whether being allergic to it influences asthma and allergy
2) Whether the levels of certain hormones, particularly sex hormones, influence asthma and allergy in adults
3) Whether some genetic patterns or profiles are associated with having asthma, severe asthma or other allergic conditions

Why was I chosen?
You recently completed and returned a questionnaire as part of a survey on asthma and allergies in Bromley. In this questionnaire you indicated you were willing to be contacted again regarding further research.

Before you decide whether or not you wish to take part in this study, please read carefully the information below or talk to others about it. You can also talk to us if anything is unclear.

Do I have to take part?
If you decide to take part, your participation may assist in finding out the causes of allergy and asthma. However, if you decide not to take part in this study, you don't have to give any explanation. This will not affect your future medical care. You may withdraw from the study at any time without giving a reason and without it affecting any health care or any treatment you currently receive (or may receive in the future).

What will happen to me if I take part?
If you decide to take part in this survey we will arrange for you to see the research team in the research centre at Hawes Down clinic. You will only need to come and see the research team once and the visit will last about one hour and forty-five minutes. If you take any medication for asthma, we will ask you to bring it with you to the clinic.
If you smoke, we would like you to avoid smoking before the appointment.
When you arrive at the clinic; we will explain the study to you and answer any questions you may have about the study. If you are happy to continue we will ask you to sign a consent form stating you agree to be involved in the study. You can agree to take part in all, or only some, aspects of the study. A copy of the consent form will be posted for you to keep. We will then:

1. Conduct an interview in which we will ask you some questions about your health and lifestyle
2. If you are female, ask you to complete a questionnaire asking questions relating to your menstrual and gynaecological history
3. Make some measurements of your height, weight, waist and hips.
4. Perform a lung function test. You will be required to blow into a machine (spirometer); which measures how fast air can be blown out of your lungs. This test will be done before and after you have inhaled a medicine that opens up the airways (a "bronchodilator" called Salbutamol). This medicine is commonly used by many people who have asthma or other lung diseases.
5. Conduct skin tests to see if you are allergic to some common allergens (for example: cat, dust mites, and grass pollen). This involves having several tiny pricks on the skin of your forearm.
6. Ask if we can take a blood sample of approximately 20ml from a vein in your arm. The blood sample will be sent to the National Heart and Lung Institute, Royal Brompton Campus, Imperial College London for the serum (the liquid part of the blood) to be separated and stored. Some of the serum will be sent to a research laboratory in Amsterdam and will be used to:

- Measure whether you are allergic to substances produced by a common bacteria (staphylococcus aureus) that is present in the environment and may be important for severe asthma and allergic sinusitis.
- Measure the level of some hormones in your blood – these hormones are related to the levels of oestrogen and testosterone in your blood.

The rest of the serum will be stored at National Heart and Lung Institute, Royal Brompton Campus, Imperial College London for 10 years and will be used for further laboratory tests. These tests would only investigate causes of asthma, allergy and sinusitis and would only be done once permission has been obtained from a National Research Ethics Committee.

Some of the blood we take will be used to assess your genetic make-up by testing your DNA. This information will only be used to test whether groups of people with particular genetic patterns or profiles are susceptible to developing asthma, or other allergic diseases and will not be used for any other reason (for example we will not be looking for genetic risk for any other medical conditions). Your DNA sample will be stored for 10 years.

7. Test whether you have a blocked nose by asking you to sniff into a special machine. This is a simple test that involves you taking a sharp deep sniff through your nose.
8. Test your sense of smell by asking you to sniff various scents and identify them.
9. We will reimburse the costs of your travel by bus or train to the test centre within Bromley PCT.

What are the possible disadvantages and risks of taking part?
Lung function tests are a routine test conducted by doctors and nurses in general practice and in hospital. They involve blowing into a machine which can be quite hard work – but not uncomfortable. The lung function tests are safe, but on principle we will not include you in this part of the study if you have recently had a heart attack, cataract surgery, are heavily pregnant or have any major illness that in the opinion of the researchers, may affect your ability to do the test. Salbutamol (as mentioned in point 4 above) may cause fine tremor in a small group of people for a short time but this occurs very infrequently, is minor and wears off within half an hour.

Skin prick tests on the forearm do not tend to cause any discomfort other than small bumps similar to nettle rash ***if*** you have a positive result. These may last for up to an hour and if they are itchy we will use antihistamine cream to soothe them.

Blood collection from an arm vein can sometimes cause some temporary discomfort and can occasionally result in minor local bruising.

What are the possible benefits of taking part?
In the long term your participation may help our research find the causes of asthma and allergies and describe their effects on people's lives. There will be no immediate benefits for you if you agree to help with this study, apart from finding out about your allergic status and lung function.

We will be able to give you the results of your skin allergy tests and lung function. If you wish, we will send your

results to your GP. We will not be able to give you the results of your blood tests because these tests will not be conducted until the study is finished in all the research centres (more than 6800 people will be tested in the whole of Europe). It is only when we look at all the participants' results together that the information becomes useful and your individual results will not mean very much to you or your doctor (and will not, as far as we know, have any implications for your health).

What will happen to the results of the research study?
The results of the study will be published in a leading medical journal. A summary of the study and results (but not any of your personal data or information) will be shared with the European Federation of Allergy and Airways Diseases Patients Associations and published on the public pages of the GA2LEN website at http://www.ga2len.net/

What if there is a problem?
It is very unlikely that you will be harmed by taking part in this study, However, If you have any complaints or concerns about this study, please immediately inform **Miss Mun Lim on 02073528121 ext. 3503.** If you are not satisfied with the response you may contact:

Bromley Patient Advice and Liaison Service (PALS)
Bassetts House,
Broadwater Gardens,
Orpington
BR67UA

"Imperial College holds Public Liability ("negligent harm") and Clinical Trial ("non-negligent harm") insurance policies which apply to this study. If you can demonstrate that you experienced harm or injury as a result of your participation in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. If the injury resulted from any procedure that is not part of the study, Imperial College will not be required to compensate you in this way. Your legal rights to claim compensation for injury where you can prove negligence are not affected"

Will my taking part in the study be kept confidential?
Yes. All the information about your participation in this study will be kept strictly confidential according to the Data Protection Act 1998. All the personal information will be securely stored for 10 years after which it will be destroyed. No information that identifies you will be transmitted outside this country. Only authorised researchers will have access to identifiable data. Neither your name nor any other identifiable information will be kept with the results of the tests or will appear in any publication or presentation related to this study.

What happens when the research study stops?
When we have studied four hundred people in Bromley, the study will be closed for recruitment. Researchers will analyse the information you have provided. It is possible that in about five or ten years time researchers may wish to contact you again to examine whether your health has altered. Researchers will only do this if you have indicated that you would be happy for them to do this when you are interviewed at the clinic and they have received Ethical Approval to do this.

Contacts for Further Information:
If you need any help or have any questions, do not hesitate to contact the Research Team:

Ms Mun Lim
Imperial College London
National Heart & Lung Institute
Emmanuel Kaye Building
Manresa Road
London SW3 6LR

Tel: 02073528121 ext. 3503
E-mail: m.lim@imperial.ac.uk

Thank you for considering taking part or taking time to read this sheet. *Please keep this sheet with you!*

Imperial College London

GA²LEN Global Allergy and Asthma European Network
Network of Excellence

Subject ID:
Centre No:

UK Adult Consent Form

Project –GA²LEN Follow Up Study
A Europe - wide study to assess the severity and burden of allergic diseases in a European Population.

Chief Investigator: Professor Peter Burney

Please initial each box you agree to. Put a line through any box you do not agree to.

1. I confirm that I have read and understand the participant information sheet (Version 1.0 dated 28/05/2008) for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or my legal rights being affected. ☐

3. I understand that some serum will be stored anonymously and indefinitely for future analyses and I agree that the study researchers may store these samples and analyse it again at a later date. It will be looked at specifically for research into asthma, allergy and will not be used for any other purpose. ☐

4. I understand that a sample of my DNA will be stored and analysed as part of this study. ☐

5. I agree that the study researchers may store my DNA and analyse it again at a later date. It will be looked at specifically for research into asthma, allergic disorders, other respiratory disease and sinusitis and will not be used for any other purpose. ☐

6. I am happy for any residual blood to be used in any future research into asthma and allergy. ☐

7. It is possible that in about 5-10 years time, researcher may wish to contact me again, to see if my health status has altered. I agree for health researchers to contact me again. ☐

8. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Appendix 9 GA²LEN Follow Up Study Centre ID ranges

Centre	No.	Subject ID Range
University of Ghent	1	10,000 – 19,999
UVMS, Austria	4	40,000 – 49,999
OUH , Denmark	5	50,000 – 59,999
HUCH, Finland	6	60,000 – 69,999
INSERM, France	7	70,000 – 79,999
Charité, Germany	8	80,000 – 89,999
Universität München (LMU)	9	90,000 – 99,999
TUM, Germany	10	100,000 – 109,999
NKUA, Greece	11	110,000 –119,999
CNR Palermo, Italy	12	120,000 – 129,999
CNR Rome, Italy	13	130,000 – 139,999
University of Genoa, Italy	14	140,000 – 149,999
Amsterdam AMC, The Netherlands	15	150,000 – 159,999
University of Utrecht, The Netherlands	16	160,000 – 169,999
Voksentoppen BKL, Norway	17	170,000 – 179,999
JUMCK, Krakow, Poland	18	180,000 – 189,999
Lodz MUL, Poland	19	190,000 – 199,999
Universitad de Coimbra, Portugal	20	200,000 – 209,999
IMIM Barcelona, Spain	21	210,000 – 219,999
Autonoma University of Madrid	22	220,000 – 229,999
Göteborg University, Sweden	23	230,000 – 239,999 + 700,000 – 709,999
Karolinska Institutet, Sweden	24	240,000 – 249,999
University of Zurich, SIAF	25	250,000 – 259,999
University of Southampton, UK	27	270,000 – 279,999
Imperial College London, UK	31	310,000 – 319,999
Medical University of Silesia, Poland	40	400,000 – 409,999
University of Umea, Sweden	41	410,000 – 419,999
University of Upssalla, Sweden	42	420, 000 - 429,999
Skopje	43	430,000 – 439,999
Russia 1		
Russia 2		
Russia 3		
Russia 4		
Russia 5		

Appendix 10

Instructions for registration to the GA²LEN Website

Most of the staff involved with the Survey is probably staff already working within the network and already registered with the GA²LEN website. This appendix applies to the new appointed staff.

The GA²LEN website gives Partners the possibility to register to the website in order to have access to the pages available to the GA²LEN Survey participants only. Open the webpage browsing www.ga2len.net In order to register click on the "I want to register" on the left side marked with a red circle below.

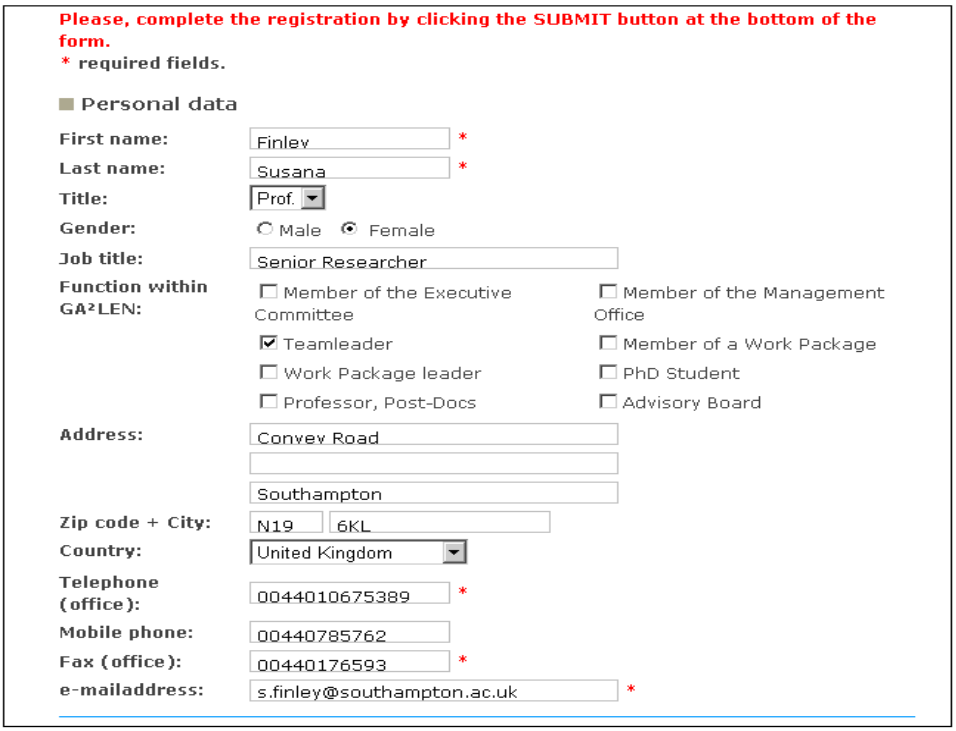
Address http://www.ga2len.net/
GA²LEN
Network of Excellence
Global Allergy and Asthma European Network
About us
Allergy & Asthma
Education
Publications
Events
Press corner
News
Videos on GA²LEN
December 12, 2006
2 videos on the GA²LEN network are available in the Videos section.
EU prioritises research on allergic diseases in the FP7
December 01, 2006
GA²LEN welcomes the vote of the European Parliament on the Seventh Framework Programme (FP7) on 30 November that acknowledges allergic diseases as major chronic diseases to be addressed in European research during the coming 7 years (2007 - 2013).
The European Union's next research programme known as the Seventh Framework Programme (FP7) will begin on 1 January 2007 and will run for seven years until 2013 with a total budget of €54.6 billion.
Read more
Partners login
Username:
Password:
- I forgot my password
- I want to register
Sponsors
Vacancies
EU research
EU Framework programme for research contract n° FOOD-CT-2004-506378
Food allergy
Site map
Contact us
Site updates
Internet

A new page http://www.ga2len.net/partners/index.cfm?action=subscribe will be opening for you to fill in a very short registration form. Just make sure you are choosing "GA2LEN Partner" as registration category, in order for you to have access to the appropriate pages.

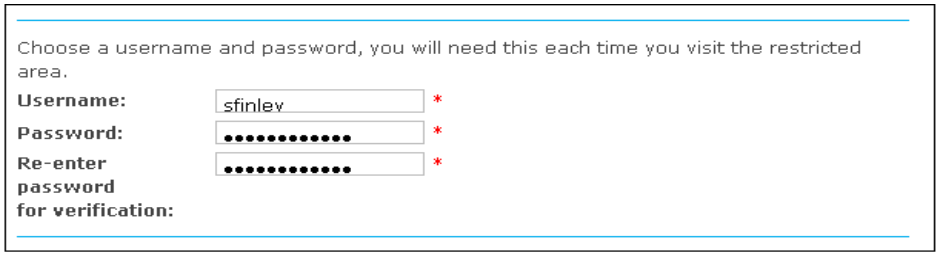
Address http://www.ga2len.net/partners/index.cfm?action=subscribe
GA²LEN
Back
Registration form GA²LEN Partners
Dear GA²LEN Participant,
Dear GA²LEN Collaborator,
Dear GA²LEN Board Member
Please, complete the form below to get access to the GA²LEN Partners zone.
This restricted web area will be an important instrument for communication amongst the GA²LEN partners.
The GA²LEN Management Office also kindly asks you to assign a restricted number of persons from within your organisation who will
be responsible to maintain your data.
Data of partners and participants can be viewed and maintained in the "Members" of the Partners zone.
Thank you for your cooperation
Sincerely Yours,
GA²LEN Office
office@ga2len.net
I want to register as a:
GA²LEN Partner
GA²LEN Collaborating Centre
Special Interested Group (Advisory board, Ethical board, Experts)
Please, complete the registration by clicking the SUBMIT button at the bottom of the form.
Internet

The registration form consists of three parts to be filled in: Personal data; Login information; Selection of partner/centre.

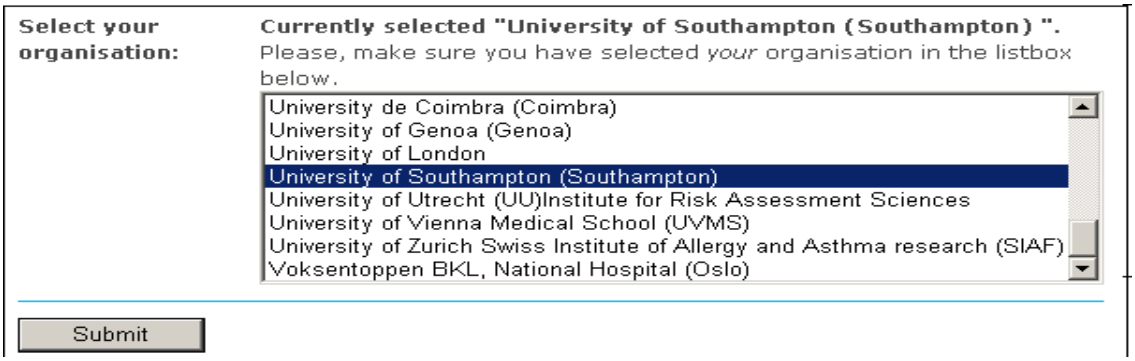
Personal data: it is extremely important to understand the significance of your email address. The given email address will be used daily by the GA²LEN Web Application for all kind of communication (e.g. Manual of Procedures dissemination). Please make sure that your email address is the most important mean of communication within the GA²LEN network.



Login information: please choose carefully your username and password.


Choose a username and password, you will need this each time you visit the restricted area.
Username: sfinley *
Password: ********** *
Re-enter password for verification: ********** *

Organisation-related information: please only select your centre from the partner list.

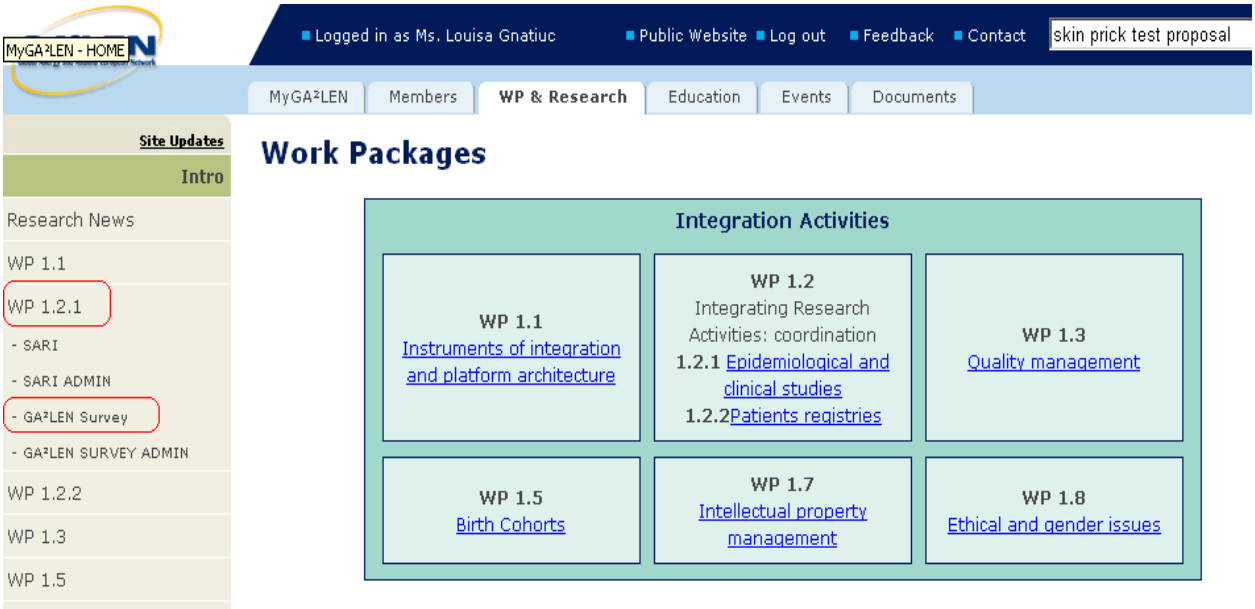

Select your organisation:
Currently selected "University of Southampton (Southampton) ".
Please, make sure you have selected your organisation in the listbox below.
University de Coimbra (Coimbra)
University of Genoa (Genoa)
University of London
University of Southampton (Southampton)
University of Utrecht (UU)Institute for Risk Assessment Sciences
University of Vienna Medical School (UVMS)
University of Zurich Swiss Institute of Allergy and Asthma research (SIAF)
Voksentoppen BKL, National Hospital (Oslo)
Submit

After you fill in and submit the form, you will receive an email on the address you provided, confirming that you have been given access to the appropriate area. When successful, a confirmation message should appear on the screen.

Every time you will log in, **"MyGA²LEN",** your personal page will open.

Click on the **WP &Research** button and you will be able to see all the Work Packages folders.
Under the WP 1.2.1, the Integration work package, you will find the GA²LEN Survey folder.

This folder will allow you, as study manager, to administer all the data and to communicate with the co-ordinating centre.

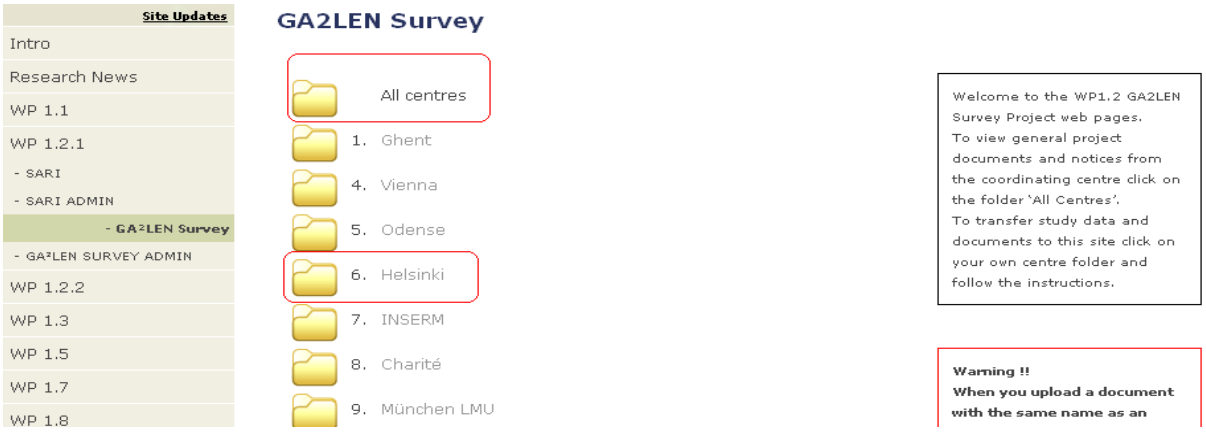


Every time you want to enter the GA²LEN Survey webpages or any Partner page, you may need to enter your user name and passwork on the partner login box on the Main page at http://www.ga2len.net.

Appendix 11
GA²LEN Survey Web Module – users manual

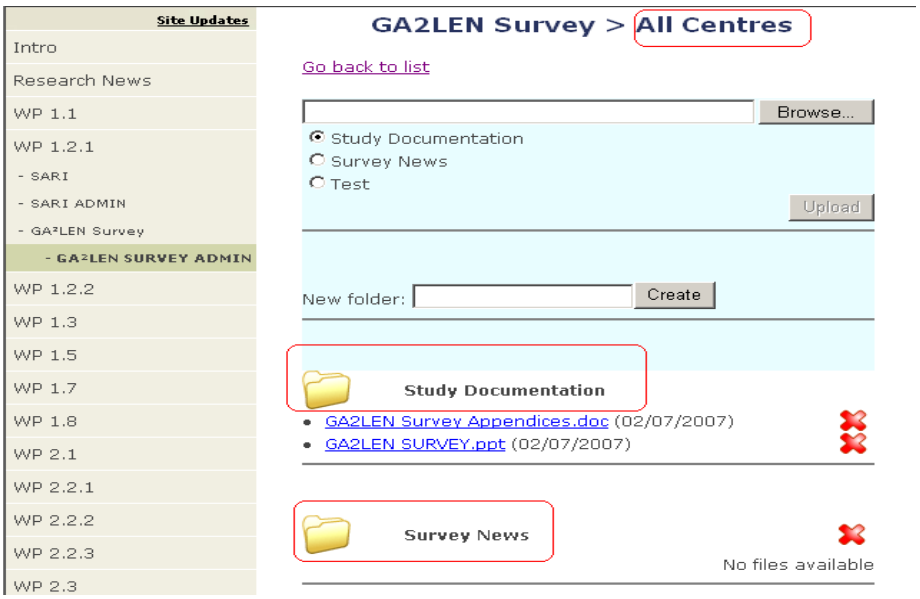
Enter the GA2LEN website, click on WP & Research, then click on GA2LEN Survey Follow Up on the left hand side, just under WP1.2.1. The overview page of the GA2LEN Survey will be opening.

General overview page
The first page of the GA²LEN Survey Follow Up Web Module is the overview page. This includes:
A welcome text on top of the page.
Contact details for the GA²LEN Survey Follow Up Co-ordinating centre
The **"All centres" folder**: every GA²LEN Survey Follow Up user has access to this folder.
The **folders for each participating centre**.



You will have access to your centre's folders **only.** Your centre's main folder is not gray out.

The "**All Centers**" page
If you click on the "All centres" folder in the general overview page, you will access the All Centres page. The purpose of this page is to allow the project coordinators to upload and distribute project documents and files. You should check this file intermittently for project news and notices.

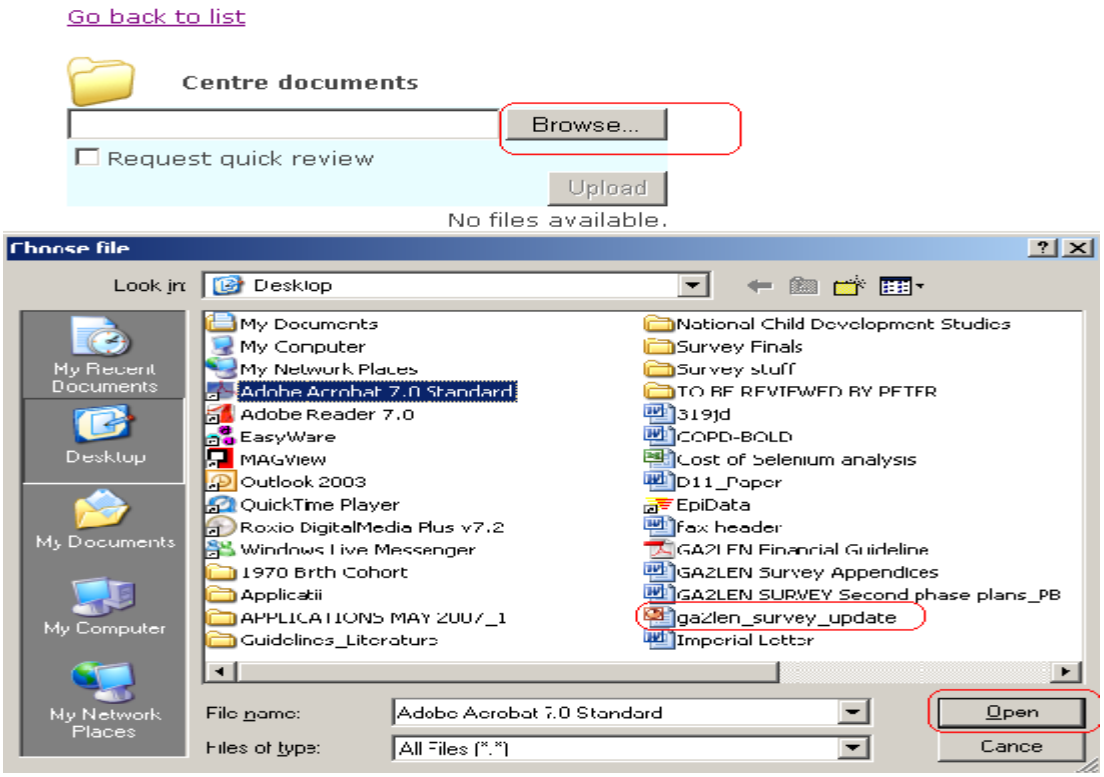


Your centre's upload page
Go back to the general overview page. If you click on your centre's folder you will enter the upload page.
The page is organized into 2 folders:

- **Centre documents**
- **Data Files**

Every folder has an upload form and a file list. Always upload files and data to the appropriate file. To upload a file, click on "Browse" button of the folder you want to upload your files. A "Choose file" window will be appearing on your screen. You have to identify the document to be uploaded, click on it then click on "Open."To complete the upload procedure, press the "Upload" button. The file will be uploaded to the folder you were working in.

If you want to request a quick review by the coordinating centre, select the checkbox near the text "Request quick review". This will send any automatic email to the coordinating centre to notify them of the transfer.



You can view which files you have uploaded to each folder by clicking the link "Show list". The folder icon will open and list its contents.

Centre documents – please transfer all **non-data** centre specific documents here:

- forward and back translations of the Survey Source Questionnaire
- sampling plans
- evidence of local permissions
- short reports

Data Files – please transfer all your data related documents here:

- dummy data entry test of the 5 questionnaire responses
- data file **(validated and cleaned)**
- transfer master file
- report on stage II & III data collection

Transferred files should be named in English, in a uniform format that clearly describes the nature of the file:
name_of_file.programme

For example a data entry test file it should be named:

data_entry_test.rec

The data file containing all the responses to the survey questionnaire should contain the name of your centre in and named like:

data_zurich.rec

This should be the double entered data file, validated and cleaned as per Epidata Manual (Section 7.4.1).

A Data collection report should be named:

data_collection_report.doc

Study Master files, should be named:

master_file_palermo.xls

Always separate words with an underscore.

The folder will only accept files that are correctly named, it will only accept a file named according to the date of transfer. The coordinating centre is automatically notified every time you upload a file to this folder.

Appendix 12

Questionnaires with answers for the data entry dummy test

File 1

I AM GOING TO ASK YOU SOME QUESTIONS. AT FIRST THESE WILL BE MOSTLY ABOUT YOUR BREATHING. WHEREVER POSSIBLE, I WOULD LIKE YOU TO ANSWER 'YES' OR 'NO'.

	NO	YES
1. Have you had wheezing or whistling in your chest at any time in the last ***12 months***?	☐	☑
IF 'NO' GO TO QUESTION 2, IF 'YES':		
1.1 Have you been at all breathless when the wheezing noise was present?	☐	☑
1.2. Have you had this wheezing or whistling when you did ***not*** have a cold?	☐	☑
2. Have you woken up with a feeling of tightness in your chest at any time in the last ***12 months***?	☑	☐
3. Have you had an attack of shortness of breath that came on during the day, when you were at rest, at any time in the last ***12 months***?	☑	☐
4. Have you had an attack of shortness of breath that came on ***following*** strenuous activity at any time in the last ***12 months***?	☐	☑
5. Have you been woken by an attack of shortness of breath at any time in the last ***12 months?***	☑	☐
IF 'NO' GO TO Q6, IF 'YES':		
5.1 Have you been woken by an attack of shortness of breath in the last ***3 months***?	☐	☐
IF 'NO' GO TO Q6, IF 'YES':		
5.1.1 ***On average*** have you been woken by an attack of shortness of breath ***at least once a week*** *in the* ***last 3 months?***	☐	☐
IF 'NO' GO TO Q6, IF 'YES':		
	TIMES	
5.1.1.1 How many times a week ***on average*** have you been woken by shortness of breath in the ***last 3 months***?	☐☐	
6. Have you been woken by an attack of coughing at any time in the ***last 12 months***?	☑	☐
7. Do you ***usually*** cough first thing in the morning in the winter? **[IF DOUBTFUL, USE QUESTION 8.1 TO CONFIRM]**	☑	☐
8. Do you ***usually*** cough during the day, or at night, in the winter?	☑	☐
IF 'NO' GO TO QUESTION 9, IF 'YES':		
8.1 Do you cough like this on most days for as much as three months each year?	☐	☐
9. Do you ***usually*** bring up any phlegm from your chest first thing in the morning in the winter? **[IF DOUBTFUL, USE QUESTION 10.1 TO CONFIRM]**	☑	☐

NO YES

10.Do you ***usually*** bring up any phlegm from your chest during the day, or at night, in the winter? NO ✓ YES ☐

'NO' GO TO QUESTION 11, IF 'YES':

NO YES

10.1 Do you bring up phlegm like this on most days for as much as three months each year? NO ☐ YES ☐

NO YES

11. Are you disabled from walking by a condition ***other than*** heart or lung disease? NO ✓ YES ☐

IF 'YES' STATE TYPE OF CONDITION IN THE BOX BELOW AND GO TO QUESTION 12, IF 'NO' GO TO Q11.1:

a) bone and joint problems	a	☐
b) neurological including stroke	b	☐
c) vascular including amputations	c	☐
d) accidents	d	☐
e) other	e	☐
NOW GO TO Q12		☐

NO YES

11.1 Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? NO ☐ YES ☐ ***IF 'NO' GO TO QUESTION 12, IF 'YES':***

NO YES

11.1.1 Do you get short of breath walking with other people of your own age on level ground? NO ☐ YES ☐ ***IF 'NO' GO TO QUESTION 12, IF 'YES':***

NO YES

11.1.1.1 Do you have to stop for breath when walking at your own pace on level ground? NO ☐ YES ☐

NO YES

12. Have you ***ever*** had asthma? NO ☐ YES ✓

IF 'NO' GO TO QUESTION 13, IF 'YES':

NO YES

12.1 Was this confirmed by a doctor? NO ☐ YES ✓

YEARS

12.2 How old were you when you had your first attack of asthma? 1 1

YEARS

12.3 How old were you when you had your most recent attack of asthma? 3 3

NO YES

12.4 Have you had an attack of asthma in the last ***12 months***? NO ✓ YES ☐

IF 'NO' GO TO 12.7, IF' YES':

ATTACKS

12.5 How many attacks of asthma have you had in the last ***12 months***? ☐☐

IF 'NONE', GO TO 12.7, IF 'YES':

ATTACKS

12.6 How many attacks of asthma have you had in the last ***3 months***? ☐☐

12.7 How many times have you woken up because of your asthma in the last ***3 months?*** TICK ONE BOX ONLY

a) every night or almost every night	a	☐
b) more than once a week, but not most nights	b	☐
c) at least twice a month, but not more than once a week	c	☐
d) less than twice a month	d	☐
e) not at all	e	✓

12.8. How often have you had trouble with your breathing because of your asthma in the last ***3 months?*** TICK ONE BOX ONLY

a) continuously	a	☐
b) about once a day	b	☐
c) at least once a week, but less than once a day	c	✓

d) less than once a week	d	
e) not at all	e	

	NO	YES
12.9 Are you currently taking any medicines including inhalers, aerosols or tablets for asthma?		✓
13. Do you have any nasal allergies, including hay fever?		✓

IF 'NO' GO TO Q14, IF' YES':

	YEARS
13.1 How old were you when you first had hay fever or nasal allergy?	1 1

	NO	YES
14. Have you ***ever*** had a problem with sneezing, or a runny or a blocked nose when you did not have a cold or the flu?		✓

IF 'NO' GO TO Q17, IF 'YES':

	NO	YES
14.1. Have you had a problem with sneezing or a runny or a blocked nose when you did not have a cold or the flu ***in the last 12 months***?		✓

IF 'NO' GO TO Q15, IF' YES':

	NO	YES
14.1.1. Has this nose problem been accompanied by itchy or watery eyes?		✓

14.1.2. In which months of the year did this nose problem occur?	NO	YES
January	✓	
February	✓	
March		✓
April		✓
May		✓
June		✓
July		✓
August		✓
September		✓
October	✓	
November	✓	
December	✓	

14.1.3. Is this set off by:	NO	YES
Grass pollen		✓
Tree pollen		✓
Weed pollen	✓	
Moulds	✓	
Animals		✓
Perfumes, smells or smoke		✓
Changes in the temperature	✓	
Changes in position (such as lying down)	✓	

	NO	YES
15. ***In the last 5 years*** have you used any medication to treat problems in your nose, or hayfever?		✓
16. In the last 5 years have you ever used **nasal** steroids?	✓	

IF 'NO' GO TO QUESTION 17 IF 'YES':

	YEARS
16.1. How old were you when you first started to use **nasal** steroids?	

NO YES

16.2. Have you used **nasal** steroids ***every year*** in the last 5 years? ☐ ☐
IF 'NO' GO TO QUESTION 16.3, IF 'YES':

MONTHS

16.2.1. On average how many months each year have you taken them? ☐☐
NOW GO TO Q17

YEARS

16.3 How many of the last 5 years have you taken **nasal** steroids? ☐☐

MONTHS

16.4. On average how many months of each of these years have you taken them? ☐☐

NO YES

17. In the last 5 years have you ever used **antihistamine as tablets, medicines, nasal sprays or eye drops?** ***IF NO, GO TO QUESTION 18*** ☐ ✓

YEARS

17.1. How old were you when you first started to use these **antihistamines**? 1 1

NO YES

17.2. Have you used these **antihistamines** ***every year*** in the last 5 years? ☐ ✓
IF 'NO' GO TO QUESTION 17.3, IF'YES':

MONTHS

17.2.1. On average how many months each year have you taken them? 1 2
NOW GO TO Q18

YEARS

17.3 How many of the last 5 years have you taken **antihistamines**? ☐☐

MONTHS

17.4. On average how many months of each of these years have you taken them? ☐☐

NO YES

18**.** Has your nose been blocked **<u>for more than 12 weeks during the last 12 months?</u>** ✓ ☐
IF 'NO' GO TO Q19, IF 'YES':

YEARS

18.1 How old were you when you first had this symptom? ☐☐

18.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

NO YES

19. Have you had pain or pressure around the forehead, nose or eyes **<u>for more than 12 weeks during the last 12 months</u>?** ✓ ☐
IF 'NO' GO TO Q20, IF 'YES':

YEARS

19.1 How old were you when you first had this symptom? ☐☐

19.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

NO YES

20**.** Have you had discoloured nasal discharge (snot) or discoloured mucus in the throat **for more than 12 weeks during the last 12 months?** ☐ ✓

IF 'NO' GO TO QUESTION 21, IF 'YES':

YEARS

20.1 How old were you when you first had this symptom? ☐☐

20.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all a ☐
b) Less than once a week b ☐
c) At least once a week, but less than once a day c ☐
d) About once a day d ☐
e) Continuously e ☐

NO YES

21**.** Has your sense of smell been reduced or absent **for more than 12 weeks during the last 12 months?** ✓ ☐

IF 'NO' GO TO QUESTION 22, IF 'YES':

YEARS

21.1 How old were you when you first had this symptom? ☐☐

21.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all a ☐
b) Less than once a week b ☐
c) At least once a week, but less than once a day c ☐
d) About once a day d ☐
e) Continuously e ☐

NO YES

22. Have you had mucus in your throat **for more than 12 weeks during the last 12 months**? ✓ ☐

IF 'NO' GO TO QUESTION 23, IF 'YES':

YEARS

22.1 How old were you when you first had this symptom? ☐☐

22.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all a ☐
b) Less than once a week b ☐
c) At least once a week, but less than once a day c ☐
d) About once a day d ☐
e) Continuously e ☐

NO YES

23**.** Has a doctor ***ever*** told you that you have **chronic** sinusitis or nasal polyps? ✓ ☐

IF 'NO' GO TO QUESTION 24, IF 'YES':

YEARS

23.1 How old were you when you first had sinusitis OR nasal polyps? ☐☐

YEARS

23.2 How old were you when you were first diagnosed as having chronic sinusitis OR nasal polyps? ☐☐

23.3. How did your sinus problems start? TICK ONE BOX ONLY

a) Headache or pressure over the sinuses a ☐
b) Loss of smell b ☐
c) A common cold c ☐
d) Frequent episodes of acute sinusitis d ☐
e) None of the above e ☐

23.4 If you also get asthma, how does this relate to your sinus problems? TICK ONE BOX ONLY

a) I don't get asthma — a
b) Sinusitis usually comes before the asthma worsens — b
c) Asthma usually comes before the sinusitis worsens — c
d) Both usually start with a common cold — d
e) None of the above — e

23.5 If you drink alcohol does this worsen your sinus problems? NO YES N/A

23.5.1 - 4 ***IF 'NO' or N/A, skip to 23.6 ; IF 'YES', which symptoms does alcohol affect?***

	NO	YES
23.5.1 Blocked Nose		
23.5.2 Runny Nose		
23.5.3 Post nasal drip (mucus in the throat)		
23.5.4 Sneezing		

23.6 Have you ***ever*** had surgery for nasal/sinus problems? NO YES

23.7. In the last 5 years have you ever used **antibiotics for nasal/sinus problems**? NO YES
IF 'NO' GO TO QUESTION 24

23.8. How old were you when you first started to use **antibiotics for nasal/sinus problems**? YEARS

23.9. Have you used **antibiotics for nasal/sinus problems *every year*** in the last 5 years? NO YES
IF 'NO' GO TO QUESTION 23.10, IF 'YES':

23.9.1. On average how many months each year have you taken them? MONTHS
NOW GO TO Q24

23.10 How many of the last 5 years have you taken **antibiotics for nasal/sinus problems**? YEARS

23.11. On average how many months of each of these years have you taken them? MONTHS

24. Have you ***ever*** had eczema or any kind of skin allergy? NO YES ✓
IF 'NO' GO TO Q25, IF 'YES':

24.1. Was this problem ***ever*** associated with your work? NO YES ✓
IF 'NO' GO TO QUESTION 25, IF 'YES':

24.2. What job were you doing that made it worse?
____Car mechanic. _____

24.3. Do you know what caused the problem at work? NO YES ✓
IF 'YES' What was this problem?_ Think associated with engine oil _____

25. Have you ***ever*** had an itchy rash that was coming and going for at ***least 6 months***? NO YES ✓
IF 'NO' GO TO QUESTION 26, IF 'YES':

25.1. Have you had this itchy rash ***in the last 12 months?*** NO YES ✓
IF 'NO' GO TO QUESTION 26, IF 'YES':

25.1.1. Has this itchy rash ***at any time*** affected any of the following places: NO ✓ YES

the folds of the elbows, behind the knees, in front of the ankles under the buttocks or around the neck, ears or eyes?

25.1.2. Does this itchy rash affect your hands? NO ☐ YES ☑

26. Have you ***ever*** had any difficulty with your breathing after taking medicines? NO ☑ YES ☐

IF 'NO' GO TO QUESTION 27 IF 'YES':

26.1 Which medicines? _____ 26.1.1 ☐
26.1.2 ☐

27. Have you ***ever*** had a runny or a stuffy nose or sneezing after taking medicines? NO ☑ YES ☐

IF 'NO' GO TO QUESTION 28, IF 'YES':

27.1 Which medicines? _____ 27.1.1 ☐
27.1.2 ☐

28. Have you ***ever*** had uticaria, nettle rash or hives after taking medicines? NO ☑ YES ☐

IF 'NO' GO TO QUESTION 29, IF 'YES':

28.1 Which medicines? _____ 28.1.1 ☐
28.1.2 ☐

29. Have you ***ever*** had an illness or trouble caused by eating a ***particular*** food or foods? NO ☑ YES ☐

IF 'YES' GO TO QUESTION 29.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

29.1 Have you nearly always had the same illness or trouble after eating this type of food? NO ☐ YES ☐

IF 'YES' GO TO QUESTION 29.1.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

29.1.1 What type of food was this? [List up to 3]

_____29.1.1.1 ☐☐
_____29.1.1.2 ☐☐
_____29.1.1.3 ☐☐

29.1.2 Did this illness or trouble include:

	NO	YES
29.1.2.1. Itching, tingling or swelling in the mouth, lips or throat?	☐	☐
29.1.2.2. A rash, nettle sting like rash or itchy skin?	☐	☐
29.1.2.3. Diarrhoea or vomiting (other than food poisoning)?	☐	☐
29.1.2.4. Runny or stuffy nose?	☐	☐
29.1.2.5. Red, sore or running eyes?	☐	☐
29.1.2.6. Difficulty swallowing?	☐	☐
29.1.2.7. Breathlessness?	☐	☐
29.1.2.8. Stiffness in your joints?	☐	☐
29.1.2.9. Fainting or dizziness?	☐	☐
29.1.2.10. Headaches?	☐	☐

SOME FURTHER QUESTIONS

1. How old was your mother when you were born? — YEARS: 2 1

2. Were you hospitalised before the age of two years for lung disease? — NO ✓ / YES

Your parents' smoking

3. Did your father ***ever*** smoke regularly during your childhood? — NO / YES ✓ / DON'T KNOW

4. Did your mother ***ever*** smoke regularly during your childhood, or before you were born? — NO / YES ✓ / DON'T KNOW

IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 5, IF 'YES':

4.1 When your mother was pregnant, in particular with you, did she: — TICK ONE BOX ONLY

a) Stop smoking before pregnancy? — a
b) Cut down or stop during pregnancy? — b ✓
c) Smoke as usual during pregnancy? — c
d) Don't know — d

5. What country were you born in? ____England_____

6. How many brothers do or did you have? — NUMBER: 0 0

IF 'NONE' GO TO QUESTION 7, IF 'ONE OR MORE':

6.1 How many ***older*** brothers?
6.2 How many ***younger*** brothers?
6.3 How many of your brothers ever had asthma?

NUMBER

6.4 How many of your ***other*** brothers ever had eczema, skin or nasal allergy or hay fever? — NUMBER

7. How many sisters do or did you have? — NUMBER: 0 1

IF 'NONE' GO TO QUESTION 8, IF 'ONE OR MORE':

NUMBER

7.1 How many ***older*** sisters? — 0 0
7.2 How many ***younger*** sisters? — 0 1
7.3 How many of your sisters ever had asthma? — 0 0
7.4 How many of your ***other*** sisters ever had eczema, skin or nasal allergy or hay fever? — 0 0

8. Did your mother ***ever*** have asthma? — NO ✓ / YES / DON'T KNOW

9. Did your mother ***ever*** have eczema, skin or nasal allergy or hay fever? — NO / YES ✓ / DON'T KNOW

10. Did your father ***ever*** have asthma? — NO ✓ / YES / DON'T KNOW

	NO	YES	DON'T KNOW
11. Did your father ***ever*** have eczema, skin or nasal allergy or hay fever?	✓		
12. Did you regularly share your bedroom with any ***older*** children before the age of five years?	✓		
13. Did you go to a school, play-school or nursery with ***older*** children before the age of five years?		✓	
14. Did you have a serious respiratory infection before the age of five years?	✓		

	NO	YES	DONT KNOW
15. Was there a dog in your home?			
15.1 During your first year of life	✓		
15.2 When you were aged 1 to 4 years		✓	
15.3 When you were aged 5-15 years		✓	

	NO	YES	DONT KNOW
16. Was there a cat in your home?			
16.1. During your first year of life	✓		
16.2 When you were aged 1 to 4 years	✓		
16.3 When you were aged 5-15 years	✓		

17. What term best describes the place you lived most of the time when you were under the age of five years?

	TICK ONE BOX ONLY	
a) Farm	a	
b) Village in a rural area	b	
c) Small town	c	✓
d) Suburb of a city	d	
e) Inner city	e	

WORK AND EDUCATION

	NO	YES
18. Are you a full time student?	✓	

IF 'YES' GO TO QUESTION 21, IF 'NO':

	YEARS
18.1 At what age did you complete full time education?	2 4

I would now like to ask you some questions on the type of jobs that you have done.

18.2. Are you currently:	TICK ONE BOX ONLY	
Employed (including military service)	1	✓
Self employed	2	
Unemployed, looking for work	3	
Not working because of poor health	4	
Full-time house-person	5	
Full time student	6	
Retired	7	
Other	8	

NO YES

18.3 Have you ***ever*** had a job for more than three consecutive months? [ ] [✓]

IF 'NO' GO TO Q22, IF 'YES':

YEARS

18.4 How old were you when you started your first job? [1][6]

18.5. What was this first job? (*be as precise as possible*) [ ][ ][ ][ ]

___Waiter in a restraunt_____

NO YES

18.6. Would you say that allergies or breathing problems influenced your **initial** job choice? [✓] [ ]

NO YES

18.7. Would you say that allergies or breathing problems are likely to influence your **future** job choices? [ ] [✓]

NO YES

18.8. Are you currently still working in your first job (as in question 18.4)? [✓] [ ]

IF 'YE'S, GO TO Q18.11, IF 'NO':

18.9 What is your current or most recent job? [Be as precise as possible, if not working, please complete as Not Working] [ ][ ][ ][ ]

_____Researcher employed in medical research_____

YEARS

18.10 How old were you when you started working in this job? [2][8]

18.11 In this job were you: TICK ONE BOX ONLY

a) A manager working for an employer? a [ ]
b) A foreman or supervisor working for an employer? b [ ]
c) Working for an employer, but neither a manager, supervisor or foreman? c [✓]
d) Self-employed? d [ ]

NO YES

19. Does or did being at work ever make your chest tight or wheezy? [✓] [ ]

NO YES

19.1 Is or was your breathing better at weekends or holidays? [✓] [ ]

DAYS

20. How many days of work have you lost because of asthma, shortness of breath or wheezing in the last **12 months?** [**0**][**0**][**0**]

NO YES

21. Have you ever worked in a job which exposed you to vapours, gas, dust or fumes? [ ] [✓]

IF 'NO' GO TO QUESTION 22, IF 'YES':

21.1 What was or is this job? [Be as precise as possible] I*f current job write 'current job'* [ ][ ][ ][ ]

___production line operative in plastics factory_____

NO YES

22. Have you ever been involved in an incident at home, work or elsewhere that exposed you to high levels of vapours, gases or fumes? [✓] [ ]

IF NO GO TO Q23; IF YES:

22.1 When did this happen?

a) Less than a year ago a [ ]
b) Between one and five years ago b [ ]
c) More than five years ago c [ ]

22.2 Could you classify this incident as:

a) A fire or an explosion — a ☐
b) A leak or a spill — b ☐
c) (Mixing of) cleaning products — c ☐
d) Something else:_____ — d ☐

22.3 Where did this happen?

a) In your own home — a ☐
b) In your workplace — b ☐
c) Somewhere else indoors — c ☐
d) Outdoors — d ☐

22.4 Did you experience respiratory symptoms within 24 hours following this incident? — NO ☐ YES ☐

23. Have you ever had to change or leave your job because it affected your breathing? — NO ✓ YES ☐

IF 'NO' GO TO QUESTION 24 IF 'YES':

23.1 What was this job? [Be as precise as possible]

_____ ☐☐☐☐

ENVIRONMENT

24. How often do cars pass your house? — TICK ONE BOX ONLY

a) More than 80 per hour — a ☐
b) between 21and 80 per hour — b ☐
c) between 5 and 20 per hour — c ☐
d) less than 5 per hour — d ✓

25. How often do heavy vehicles (e.g. trucks/buses) pass your house? — TICK ONE BOX ONLY

a) More than 20 per hour — a ☐
b) between 4 and 20 per hour — b ☐
c) at least one but less than 4 per hour — c ☐
d) less than one per hour — d ✓

TOBACCO AND ALCOHOL

26. Have you ever smoked for as long as a year? — NO ✓ YES ☐

['YES' means at least 20 packs of cigarettes or 12 oz (360 grams) of tobacco in a lifetime, or at least one cigarette per day or one cigar a week for one year]
IF 'NO' GO TO QUESTION 27, IF 'YES':

26.1 How old were you when you started smoking? — YEARS ☐☐

26.2 Do you **now** smoke, as of ***one month ago***? — NO ☐ YES ☐

***IF 'NO' GO TO QUESTION 26.3, IF 'YES'*:**

NUMBER

26.2.1-4 How much do you ***now*** smoke on average

26.2.1 number of cigarettes ***per day*** ☐☐
26.2.2 number of cigarillos ***per day*** ☐☐
26.2.3 number of cigars ***a week*** ☐☐
26.2.4 pipe tobacco in a) ounces / ***week*** ☐☐
b) grams / ***week*** ☐☐☐

NO YES

26.3 Have you stopped or cut down smoking? ☐ ☐

IF 'NO' GO TO QUESTION 26.4, IF 'YES':

YEARS

26.3.1 How old were you when you stopped or cut down smoking? ☐☐

26.3.2. 1-4 ***on average*** of the entire time you smoked, before you stopped or cut down, how much did you smoke?

NUMBER

26.3.2.1 number of cigarettes per day	☐☐
26.3.2.2 number of cigarillos per day	☐☐
26.3.2.3 number of cigars a week	☐☐
26.3.2.4 pipe tobacco in a) ounces / week	☐☐
b) grams / week	☐☐☐

NO YES

26.4 Do you or did you inhale the smoke? ☐ ☐

NO YES

27. Have you been **regularly** exposed to tobacco smoke in the last ***12months***? ✓ ☐

['Regularly' means on most days or nights]

IF 'NO' GO TO QUESTION 28, IF 'YES':

NUMBER

27.1 Not counting yourself, how many people in your household smoke regularly? ☐☐

NO YES

27.2 Do people smoke regularly in the room where you work? ☐ ☐

HOURS

27.3 How many hours per day are you exposed to ***other people's*** tobacco smoke? ☐☐

Please provide more information.

27.5 On average how many hours per day, are you exposed to other peoples tobacco smoke In the following locations

NUMBER

a) At home	a	☐☐
b) At workplace	b	☐☐
c) In bars, restaurants, cinemas or similar social settings	c	☐☐
d) Elsewhere	d	☐☐

28. How many units of alcohol do you drink daily/weekly?

(one unit = one small bottle of beer (250 ml), a small glass of red or white wine (120 ml) or one shot of spirits (40ml))

TICK ONE BOX ONLY

a) Never	a	☐
b) Less than one a week	b	☐
c) At least one a week but less than one a day	c	☐
d) 1-3 units a day	d	✓
e) 4 units a day	e	☐
f) More than 5 units per day	f	☐

<u>MEDICINES</u>

NO YES

29. Have you used any **inhaled** medicines to help your breathing at any time in the last ***12 months***? ***IF NO' GO TO QUESTION 30, IF 'YES':*** ☐ ☒

What have you used in the last ***12 months***?

INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

NO YES

29.1 **short acting beta-2-agonist inhalers** ☐ ☒

PUFFS

29.1.1 If used, how many puffs per day have you used **in the last week?** 0 2

NO YES

29.2 **long acting beta-2-agonist inhalers** ☒ ☐

PUFFS

29.2.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

29.2.2 Is this a combination with a steroids? ☐ ☐

If YES GO TO QUESTION 29.3.2

NO YES

29.3 **inhaled steroids** **DOSE:_____** ☒ ☐

(***if combined B2 and steroid please insert inhaled steroid dose***)

PUFFS

29.3.1 If used, how many puffs per day have you used **in the last week?** ☐☐

29.3.2 If used, which one? _____ ☐☐☐

NO YES

29.4 **anti-muscarinic inhalers** ☒ ☐

PUFFS

29.4.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

30. Have you used any **pills**, **capsules**, **tablets** or **medicines**, other than inhaled medicines, to help your breathing at any time in the last ***12 months***? ✓ ☐

IF 'NO' GO TO QUESTION 31, IF 'YES':

What have you used in the last ***12 months***?

INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

NO YES

30.1 **oral methylxanthines** ✓ ☐

NO YES

30.2 **oral steroids** ✓ ☐

If used, have you used these in the last 12 months

a

a. More or less continuously ☐ b

b. More than 2 short courses in the last 12 months ☐ c

c. More than 1 short course in the last 12 months ☐ d

d. A single short course in the last 12 months ☐ e

NO YES

30.3 **oral anti-leukotrienes** ✓ ☐

NO YES

31. **<u>In the last 5 years</u>** have you ever used inhaled steroids? ☐ ✓

IF NO GO TO QUESTION 32

YEARS

31.1. How old were you when you first started to use inhaled steroids? | 1 | 3 |

	NO	YES
31.2. Have you used inhaled steroids ***every year*** in the last 5 years? ***IF NO GO TO QUESTION 31.3, IF YES***		✓

	MONTHS	
31.2.1. On average how many months each year have you taken them? ***NOW GO TO Q32***	1	2

	YEARS	
31.3 How many of the last 5 years have you taken inhaled steroids?	0	5

	MONTHS	
31.4. On average how many months of each of these years have you taken them?	1	2

USE OF HEALTH SERVICES

	NO	YES	DONT KNOW
32. Have you been vaccinated for allergy in the last 5 years? ***IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 33, IF 'YES':***	✓		

	NO	YES
32.1 Have you been vaccinated for allergy in the last ***12 months***?		

	NO	YES
33. In the last 5 years have you visited a hospital casualty department or emergency room because of breathing problems? ***IF NO GO TO Q34, IF YES***	✓	

	NO	YES
33.1. Have you visited a hospital casualty department or emergency room because of breathing problems in the ***last 12 months***? ***IF NO GO TO 34, IF YES***		

	NO	YES
33.1.1 Was this due to asthma, shortness of breath or wheezing?		

	TIMES	
33.1.2 How many times ***in the last 12 months*****?**		

34 How many nights have you spent in hospital with any of the following conditions in the last 5 years?

	NUMBER OF NIGHTS		
a) Asthma	a		0
b) Chest infection	b		0
c) COPD	c		0
d) Sinusitis	d		0
e) Other	e		0

	NO	YES
34.1 Have you spent a night in hospital in the ***last 12 months***?	✓	

	NO	YES
35. In the last 5 years have you been seen by a doctor because of breathing problems or because of shortness of breath? ***IF NO GO TO Q36, IF YES***	✓	

	NO	YES
35.1 Have you been seen by a general practitioner because of breathing problems or shortness of breath in the ***last 12 months? IF NO GO TO Q35.2, IF YES***		

	NUMBER	
35.1.1 How many times?		

	NO	YES
35.2. Have you seen a specialist (chest physician, allergy specialist, internal medicine specialist, ENT doctor) because of your breathing problems or shortness of breath ***in the last 12 months***?		

	NUMBER
35.4.1 How many times?	

	M	F
36. Gender	✓	

✓✓	DAY	MONTH	YEAR
37. Date of birth	3 1	0 5	7 3

INTERVIEW TYPE? **TICK ONE BOX ONLY**		
a) At centre face to face	a	✓
b) At home face to face	b	
c) By telephone	c	
d) Self completed at home	d	
END FIELDWORKER NUMBER		005

File 2

	NO	YES
1. Have you had wheezing or whistling in your chest at any time in the last ***12 months***?	☒	☐
IF 'NO' GO TO QUESTION 2, IF 'YES':		
1.1 Have you been at all breathless when the wheezing noise was present?	☐	☐
1.2. Have you had this wheezing or whistling when you did ***not*** have a cold?	☐	☐
2. Have you woken up with a feeling of tightness in your chest at any time in the last ***12 months***?	☒	☐
3. Have you had an attack of shortness of breath that came on during the day, when you were at rest, at any time in the last ***12 months***?	☒	☐
4. Have you had an attack of shortness of breath that came on ***following*** strenuous activity at any time in the last ***12 months***?	☒	☐
5. Have you been woken by an attack of shortness of breath at any time in the last ***12 months?***	☒	☐
IF 'NO' GO TO Q6, IF 'YES':		
5.1 Have you been woken by an attack of shortness of breath in the last ***3 months***?	☐	☐
IF 'NO' GO TO Q6, IF 'YES':		
5.1.1 ***On average*** have you been woken by an attack of shortness of breath ***at least once a week*** *in the* ***last 3 months?***	☐	☐
IF 'NO' GO TO Q6, IF 'YES':		

	TIMES
5.1.1.1 How many times a week ***on average*** have you been woken by shortness of breath in the ***last 3 months***?	☐☐

	NO	YES
6. Have you been woken by an attack of coughing at any time in the ***last 12 months***?	☒	☐
7. Do you ***usually*** cough first thing in the morning in the winter? **[IF DOUBTFUL, USE QUESTION 8.1 TO CONFIRM]**	☒	☐
8. Do you ***usually*** cough during the day, or at night, in the winter?	☒	☐
IF 'NO' GO TO QUESTION 9, IF 'YES':		
8.1 Do you cough like this on most days for as much as three months each year?	☒	☐
9. Do you ***usually*** bring up any phlegm from your chest first thing in the morning in the winter? **[IF DOUBTFUL, USE QUESTION 10.1 TO CONFIRM]**	☒	☐
10.Do you ***usually*** bring up any phlegm from your chest during the day, or at night, in the winter?	☒	☐
'NO' GO TO QUESTION 11, IF 'YES':		
10.1 Do you bring up phlegm like this on most days for as much as three months each year?	☒	☐
11. Are you disabled from walking by a condition ***other than*** heart or lung disease?	☒	☐
IF 'YES' STATE TYPE OF CONDITION IN THE BOX BELOW AND GO TO QUESTION 12, IF 'NO' GO TO Q11.1:		

a) bone and joint problems a ☐
b) neurological including stroke b ☐
c) vascular including amputations c ☐
d) accidents d ☐
e) other e ☐
NOW GO TO Q12 ☐

NO YES

11.1 Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? ***IF 'NO' GO TO QUESTION 12, IF 'YES':*** ☒ ☐

NO YES

11.1.1 Do you get short of breath walking with other people of your own age on level ground? ***IF 'NO' GO TO QUESTION 12, IF 'YES':*** ☒ ☐

NO YES

11.1.1.1 Do you have to stop for breath when walking at your own pace on level ground? ☒ ☐

NO YES

12. Have you ***ever*** had asthma? ☒ ☐
IF 'NO' GO TO QUESTION 13, IF 'YES':

NO YES

12.1 Was this confirmed by a doctor? ☐ ☐

YEARS

12.2 How old were you when you had your first attack of asthma? ☐☐

YEARS

12.3 How old were you when you had your most recent attack of asthma? ☐☐

NO YES

12.4 Have you had an attack of asthma in the last ***12 months***? ☐ ☐
IF 'NO' GO TO 12.7, IF' YES':

ATTACKS

12.5 How many attacks of asthma have you had in the last ***12 months***? ☐☐
IF 'NONE', GO TO 12.7, IF 'YES':

ATTACKS

12.6 How many attacks of asthma have you had in the last ***3 months***? ☐☐

12.7 How many times have you woken up because of your asthma in the last ***3 months?*** TICK ONE BOX ONLY
a) every night or almost every night a ☐
b) more than once a week, but not most nights b ☐
c) at least twice a month, but not more than once a week c ☐
d) less than twice a month d ☐
e) not at all e ☐

12.8. How often have you had trouble with your breathing because of your asthma in the last ***3 months?***
TICK ONE BOX ONLY
a) continuously a ☐
b) about once a day b ☐
c) at least once a week, but less than once a day c ☐
d) less than once a week d ☐
e) not at all e ☐

NO YES

12.9 Are you currently taking any medicines including inhalers, aerosols or tablets for asthma? ☐ ☐

NO YES

13. Do you have any nasal allergies, including hay fever? ☐ ☒

IF 'NO' GO TO Q14, IF' YES':

YEARS

13.1 How old were you when you first had hay fever or nasal allergy? 2 4

NO YES

14. Have you ***ever*** had a problem with sneezing, or a runny or a blocked nose when you did not have a cold or the flu? ☐ ☒

IF 'NO' GO TO Q17, IF 'YES':

NO YES

14.1. Have you had a problem with sneezing or a runny or a blocked nose when you did not have a cold or the flu ***in the last 12 months***? ☐ ☒

IF 'NO' GO TO Q15, IF' YES':

NO YES

14.1.1. Has this nose problem been accompanied by itchy or watery eyes? ☐ ☒

14.1.2. In which months of the year did this nose problem occur?

	NO	YES
January	☐	☐
February	☐	☐
March	☐	☒
April	☐	☒
May	☐	☒
June	☐	☒
July	☐	☒
August	☐	☐
September	☐	☐
October	☐	☐
November	☐	☐
December	☐	☐

14.1.3. Is this set off by:

	NO	YES
Grass pollen	☐	☒
Tree pollen	☐	☒
Weed pollen	☐	☒
Moulds	☐	☐
Animals	☐	☐
Perfumes, smells or smoke	☐	☐
Changes in the temperature	☐	☐
Changes in position (such as lying down)	☐	☐

NO YES

15. ***In the last 5 years*** have you used any medication to treat problems in your nose, or hayfever? ☐ ☒

NO YES

16. In the last 5 years have you ever used **nasal** steroids? ☐ ☒

IF 'NO' GO TO QUESTION 17 IF 'YES':

YEARS

16.1. How old were you when you first started to use **nasal** steroids? **28** ®8

NO YES

16.2. Have you used **nasal** steroids ***every year*** in the last 5 years? ☐ ☒

IF 'NO' GO TO QUESTION 16.3, IF 'YES':

MONTHS

16.2.1. On average how many months each year have you taken them?

NOW GO TO Q17

YEARS

16.3 How many of the last 5 years have you taken **nasal** steroids? **5 years** ☐☐

16.4. On average how many months of each of these years have you taken them? **3 mths** MONTHS ☐☐

17. In the last 5 years have you ever used **antihistamine tablets, medicines, nasal sprays or eye drops?** ***IF NO, GO TO QUESTION 18*** NO ☐ YES ☒

17.1. How old were you when you first started to use these **antihistamines**? **24 yrs** YEARS ☐☐

17.2. Have you used these **antihistamines** ***every year*** in the last 5 years? NO ☐ YES ☒
IF 'NO' GO TO QUESTION 17.3, IF'YES':

17.2.1. On average how many months each year have you taken them? MONTHS ☐☐
NOW GO TO Q18

17.3 How many of the last 5 years have you taken **antihistamines**? **5 yrs** YEARS ☐☐

17.4. On average how many months of each of these years have you taken them? **5 mths** MONTHS ☐☐

18**.** Has your nose been blocked **<u>for more than 12 weeks during the last 12 months?</u>** NO ☒ YES ☐
IF 'NO' GO TO Q19, IF 'YES':

18.1 How old were you when you first had this symptom? **24 yrs** YEARS ☐☐

18.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☒
e) Continuously	e ☐

19. Have you had pain or pressure around the forehead, nose or eyes **<u>for more than 12 weeks during the last 12 months</u>?** NO ☐ YES ☒
IF 'NO' GO TO Q20, IF 'YES':

19.1 How old were you when you first had this symptom? **28 yrs** YEARS ☐☐

19.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☒
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

20**.** Have you had discoloured nasal discharge (snot) or discoloured mucus in the throat **<u>for more than 12 weeks during the last 12 months</u>?** NO ☒ YES ☐
IF 'NO' GO TO QUESTION 21, IF 'YES':

20.1 How old were you when you first had this symptom? YEARS ☐☐

20.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all — a ☒
b) Less than once a week — b ☐
c) At least once a week, but less than once a day — c ☐
d) About once a day — d ☐
e) Continuously — e ☐

21. Has your sense of smell been reduced or absent **for more than 12 weeks during the last 12 months?** NO ☒ YES ☐

IF 'NO' GO TO QUESTION 22, IF 'YES':

21.1 How old were you when you first had this symptom? YEARS ☐☐

21.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all — a ☒
b) Less than once a week — b ☐
c) At least once a week, but less than once a day — c ☐
d) About once a day — d ☐
e) Continuously — e ☐

22. Have you had mucus in your throat **for more than 12 weeks during the last 12 months**? NO ☒ YES ☐

IF 'NO' GO TO QUESTION 23, IF 'YES':

22.1 How old were you when you first had this symptom? YEARS ☐☐

22.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all — a ☒
b) Less than once a week — b ☐
c) At least once a week, but less than once a day — c ☐
d) About once a day — d ☐
e) Continuously — e ☐

23. Has a doctor ***ever*** told you that you have **chronic** sinusitis or nasal polyps? NO ☒ YES ☐

IF 'NO' GO TO QUESTION 24, IF 'YES':

23.1 How old were you when you first had sinusitis OR nasal polyps? YEARS ☐☐

23.2 How old were you when you were first diagnosed as having chronic sinusitis OR nasal polyps? YEARS ☐☐

23.3. How did your sinus problems start? TICK ONE BOX ONLY

a) Headache or pressure over the sinuses — a ☐
b) Loss of smell — b ☐
c) A common cold — c ☐
d) Frequent episodes of acute sinusitis — d ☐
e) None of the above — e ☒

23.4 If you also get asthma, how does this relate to your sinus problems? TICK ONE BOX ONLY

a) I don't get asthma — a ☒
b) Sinusitis usually comes before the asthma worsens — b ☐
c) Asthma usually comes before the sinusitis worsens — c ☐

d) Both usually start with a common cold d ☐
e) None of the above e ☐

23.5 If you drink alcohol does this worsen your sinus problems? NO ☐ YES ☐ N/A ☒

23.5.1 - 4 ***IF 'NO' or N/A, skip to 23.6 ; IF 'YES', which symptoms does alcohol affect?***

	NO	YES
23.5.1 Blocked Nose	☐	☐
23.5.2 Runny Nose	☐	☐
23.5.3 Post nasal drip (mucus in the throat)	☐	☐
23.5.4 Sneezing	☐	☐

23.6 Have you ***ever*** had surgery for nasal/sinus problems? NO ☒ YES ☐

23.7. In the last 5 years have you ever used **antibiotics for nasal/sinus problems**? NO ☒ YES ☐
IF 'NO' GO TO QUESTION 24

23.8. How old were you when you first started to use **antibiotics for nasal/sinus problems**? YEARS ☐☐

23.9. Have you used **antibiotics for nasal/sinus problems *every year*** in the last 5 years? NO ☒ YES ☐
IF 'NO' GO TO QUESTION 23.10, IF 'YES':

23.9.1. On average how many months each year have you taken them? MONTHS ☐☐
NOW GO TO Q24

23.10 How many of the last 5 years have you taken **antibiotics for nasal/sinus problems**? YEARS ☐☐

23.11. On average how many months of each of these years have you taken them? MONTHS ☐☐

24. Have you ***ever*** had eczema or any kind of skin allergy? NO ☐ YES ☒
IF 'NO' GO TO Q25, IF 'YES':

24.1. Was this problem ***ever*** associated with your work? NO ☐ YES ☒
IF 'NO' GO TO QUESTION 25, IF 'YES':

24.2. What job were you doing that made it worse? ☐☐☐☐
_____

24.3. Do you know what caused the problem at work? NO ☐ YES ☒
IF 'YES' What was this problem?_____

25. Have you ***ever*** had an itchy rash that was coming and going for at ***least 6 months***? NO ☐ YES ☒
***IF 'NO' GO TO QUESTION 26, IF 'YES'*:**

25.1. Have you had this itchy rash ***in the last 12 months?*** NO ☐ YES ☒
IF 'NO' GO TO QUESTION 26, IF 'YES':

25.1.1. Has this itchy rash ***at any time*** affected any of the following places: the folds of the elbows, behind the knees, in front of the ankles under the buttocks or around the neck, ears or eyes? NO ☐ YES ☒

25.1.2. Does this itchy rash affect your hands? NO ☒ YES ☐

NO YES

26. Have you ***ever*** had any difficulty with your breathing after taking medicines? ☒ ☐

IF 'NO' GO TO QUESTION 27 IF 'YES':

26.1 Which medicines? _____ 26.1.1 ☐
26.1.2 ☐

NO YES

27. Have you ***ever*** had a runny or a stuffy nose or sneezing after taking medicines? ☒ ☐

IF 'NO' GO TO QUESTION 28, IF 'YES':

27.1 Which medicines? _____ 27.1.1 ☐
27.1.2 ☐

NO YES

28. Have you ***ever*** had uticaria, nettle rash or hives after taking medicines? ☒ ☐

IF 'NO' GO TO QUESTION 29, IF 'YES':

28.1 Which medicines? _____ 28.1.1 ☐
28.1.2 ☐

NO YES

29. Have you ***ever*** had an illness or trouble caused by eating a ***particular*** food or foods? ☒ ☐

IF 'YES' GO TO QUESTION 29.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

NO YES

29.1 Have you nearly always had the same illness or trouble after eating this type of food? ☐ ☐

IF 'YES' GO TO QUESTION 29.1.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

29.1.1 What type of food was this? [List up to 3]

_____29.1.1.1 ☐☐
_____29.1.1.2 ☐☐
_____29.1.1.3 ☐☐

29.1.2 Did this illness or trouble include:

	NO	YES
29.1.2.1. Itching, tingling or swelling in the mouth, lips or throat?	☐	☐
29.1.2.2. A rash, nettle sting like rash or itchy skin?	☐	☐
29.1.2.3. Diarrhoea or vomiting (other than food poisoning)?	☐	☐
29.1.2.4. Runny or stuffy nose?	☐	☐
29.1.2.5. Red, sore or running eyes?	☐	☐
29.1.2.6. Difficulty swallowing?	☐	☐
29.1.2.7. Breathlessness?	☐	☐
29.1.2.8. Stiffness in your joints?	☐	☐
29.1.2.9. Fainting or dizziness?	☐	☐
29.1.2.10. Headaches?	☐	☐

SOME FURTHER QUESTIONS

1. How old was your mother when you were born? — YEARS: 23

2. Were you hospitalised before the age of two years for lung disease? — NO ☐ YES ☒

Your parents' smoking

3. Did your father ***ever*** smoke regularly during your childhood? — NO ☒ YES ☐ DON'T KNOW ☐

4. Did your mother ***ever*** smoke regularly during your childhood, or before you were born? — NO ☒ YES ☐ DON'T KNOW ☐

IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 5, IF 'YES':

4.1 When your mother was pregnant, in particular with you, did she: — TICK ONE BOX ONLY

a) Stop smoking before pregnancy? a ☐
b) Cut down or stop during pregnancy? b ☐
c) Smoke as usual during pregnancy? c ☐
d) Don't know d ☐

5. What country were you born in? _____ ☐☐☐

6. How many brothers do or did you have? — NUMBER: 2
IF 'NONE' GO TO QUESTION 7, IF 'ONE OR MORE':

NUMBER

6.1 How many ***older*** brothers? ☐☐
6.2 How many ***younger*** brothers? 2☐
6.3 How many of your brothers ever had asthma? 0☐

6.4 How many of your ***other*** brothers ever had eczema, skin or nasal allergy or hay fever? — NUMBER: 0☐

7. How many sisters do or did you have? — NUMBER: 1☐
IF 'NONE' GO TO QUESTION 8, IF 'ONE OR MORE':

NUMBER

7.1 How many ***older*** sisters? 1☐
7.2 How many ***younger*** sisters? 4☐
7.3 How many of your sisters ever had asthma? 0☐
7.4 How many of your ***other*** sisters ever had eczema, skin or nasal allergy or hay fever? 2☐

8. Did your mother ***ever*** have asthma? — NO ☒ YES ☐ DON'T KNOW ☐

9. Did your mother ***ever*** have eczema, skin or nasal allergy or hay fever? — NO ☒ YES ☐ DON'T KNOW ☐

10. Did your father ***ever*** have asthma? — NO ☒ YES ☐ DON'T KNOW ☐

	NO	YES	DON'T KNOW
11. Did your father ***ever*** have eczema, skin or nasal allergy or hay fever?	☒	☐	☐
12. Did you regularly share your bedroom with any ***older*** children before the age of five years?	☐	☒	☐
13. Did you go to a school, play-school or nursery with ***older*** children before the age of five years?	☒	☐	☐
14. Did you have a serious respiratory infection before the age of five years?	☐	☒	☐

	NO	YES	DONT KNOW
15. Was there a dog in your home?			
15.1 During your first year of life	☒	☐	☐
15.2 When you were aged 1 to 4 years	☒	☐	☐
15.3 When you were aged 5-15 years	☒	☐	☐

	NO	YES	DONT KNOW
16. Was there a cat in your home?			
16.1. During your first year of life	☒	☐	☐
16.2 When you were aged 1 to 4 years	☒	☐	☐
16.3 When you were aged 5-15 years	☒	☐	☐

17. What term best describes the place you lived most of the time when you were under the age of five years?

TICK ONE BOX ONLY

a) Farm	a	☐
b) Village in a rural area	b	☐
c) Small town	c	☐
d) Suburb of a city	d	☐
e) Inner city	e	☒

<u>WORK AND EDUCATION</u>

	NO	YES
18. Are you a full time student?	☒	☐

IF 'YES' GO TO QUESTION 21, IF 'NO':

	YEARS
18.1 At what age did you complete full time education?	24 ☐

I would now like to ask you some questions on the type of jobs that you have done.

18.2. Are you currently: TICK ONE BOX ONLY

Employed (including military service)	1	☒
Self employed	2	☐
Unemployed, looking for work	3	☐
Not working because of poor health	4	☐
Full-time house-person	5	☐
Full time student	6	☐
Retired	7	☐
Other	8	☐

	NO	YES
18.3 Have you ***ever*** had a job for more than <u>three consecutive months</u>?	☐	☒

IF 'NO' GO TO Q22, IF 'YES':

YEARS

18.4 How old were you when you started your first job? ☐☐

18.5. What was this first job? (*be as precise as possible*) ☐☐☐☐

_____

NO YES

18.6. Would you say that allergies or breathing problems influenced your **initial** job choice? ☒ ☐

NO YES

18.7. Would you say that allergies or breathing problems are likely to influence your **future** job choices? ☒ ☐

NO YES

18.8. Are you currently still working in your first job (as in question 18.4)? ☒ ☐

IF 'YE'S, GO TO Q18.11, IF 'NO':

18.9 What is your current or most recent job? [Be as precise as possible, if not working, please complete as Not Working]

_____ ☐☐☐☐

YEARS

18.10 How old were you when you started working in this job? ☐☐

18.11 In this job were you: TICK ONE BOX ONLY

a) A manager working for an employer?	a	☐
b) A foreman or supervisor working for an employer?	b	☐
c) Working for an employer, but neither a manager, supervisor or foreman?	c	☒
d) Self-employed?	d	☐

NO YES

19. Does or did being at work ever make your chest tight or wheezy? ☒ ☐

NO YES

19.1 Is or was your breathing better at weekends or holidays? ☒ ☐

DAYS

20. How many days of work have you lost because of asthma, shortness of breath or wheezing in the last **12 months?** ☐☐☐

NO YES

21. Have you ever worked in a job which exposed you to vapours, gas, dust or fumes? ☐ ☒

IF 'NO' GO TO QUESTION 22, IF 'YES':

21.1 What was or is this job? [Be as precise as possible] I*f current job write 'current job'* ☐☐☐☐

_____

NO YES

22. Have you ever been involved in an incident at home, work or elsewhere that exposed you to high levels of vapours, gases or fumes? ☒ ☐

IF NO GO TO Q23; IF YES:

22.1 When did this happen?

a) Less than a year ago	a	☐
b) Between one and five years ago	b	☐
c) More than five years ago	c	☐

22.2 Could you classify this incident as:

a) A fire or an explosion	a	☐
b) A leak or a spill	b	☐

c) (Mixing of) cleaning products c ☐
d) Something else:_____ d ☐

22.3 Where did this happen?
a) In your own home a ☐
b) In your workplace b ☐
c) Somewhere else indoors c ☐
d) Outdoors d ☐

22.4 Did you experience respiratory symptoms within 24 hours following this incident? NO ☐ YES ☐

23. Have you ever had to change or leave your job because it affected your breathing? NO ☒ YES ☐
IF 'NO' GO TO QUESTION 24 IF 'YES':
23.1 What was this job? [Be as precise as possible]
_____ ☐☐☐☐

ENVIRONMENT

24. How often do cars pass your house? TICK ONE BOX ONLY
a) More than 80 per hour a ☐
b) between 21and 80 per hour b ☐
c) between 5 and 20 per hour c ☒
d) less than 5 per hour d ☐

25. How often do heavy vehicles (e.g. trucks/buses) pass your house? TICK ONE BOX ONLY
a) More than 20 per hour a ☐
b) between 4 and 20 per hour b ☐
c) at least one but less than 4 per hour c ☒
d) less than one per hour d ☐

TOBACCO AND ALCOHOL

26. Have you ever smoked for as long as a year? NO ☒ YES ☐
['YES' means at least 20 packs of cigarettes or 12 oz (360 grams) of tobacco in a lifetime, or at least one cigarette per day or one cigar a week for one year]
IF 'NO' GO TO QUESTION 27, IF 'YES':

26.1 How old were you when you started smoking? YEARS ☐☐

26.2 Do you **now** smoke, as of ***one month ago***? NO ☐ YES ☐
***IF 'NO' GO TO QUESTION 26.3, IF 'YES'*:**

NUMBER

26.2.1-4 How much do you ***now*** smoke on average
26.2.1 number of cigarettes ***per day*** ☐☐
26.2.2 number of cigarillos ***per day*** ☐☐
26.2.3 number of cigars ***a week*** ☐☐
26.2.4 pipe tobacco in a) ounces / ***week*** ☐☐
b) grams / ***week*** ☐☐☐

26.3 Have you stopped or cut down smoking? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 26.4, IF 'YES':

YEARS

26.3.1 How old were you when you stopped or cut down smoking? ☐☐

26.3.2. 1-4 ***on average*** of the entire time you smoked, before you stopped or cut down, how much did you smoke? NUMBER

26.3.2.1 number of cigarettes per day	☐☐
26.3.2.2 number of cigarillos per day	☐☐
26.3.2.3 number of cigars a week	☐☐
26.3.2.4 pipe tobacco in a) ounces / week	☐☐
b) grams / week	☐☐☐

26.4 Do you or did you inhale the smoke? NO ☐ YES ☐

27. Have you been **regularly** exposed to tobacco smoke in the last ***12months***? NO ☒ YES ☐
['Regularly' means on most days or nights]

IF 'NO' GO TO QUESTION 28, IF 'YES':

27.1 Not counting yourself, how many people in your household smoke regularly? NUMBER ☐☐

27.2 Do people smoke regularly in the room where you work? NO ☒ YES ☐

27.3 How many hours per day are you exposed to ***other people's*** tobacco smoke? HOURS ☐☐

Please provide more information.

27.6 On average how many hours per day, are you exposed to other peoples tobacco smoke In the following locations

		NUMBER
a) At home	a	☐☐
b) At workplace	b	☐☐
c) In bars, restaurants, cinemas or similar social settings	c	☐☐
d) Elsewhere	d	☐☐

28. How many units of alcohol do you drink daily/weekly?
(one unit = one small bottle of beer (250 ml), a small glass of red or white wine (120 ml) or one shot of spirits (40ml))

		TICK ONE BOX ONLY
a) Never	a	☒
b) Less than one a week	b	☐
c) At least one a week but less than one a day	c	☐
d) 1-3 units a day	d	☐
e) 4 units a day	e	☐
f) More than 5 units per day	f	☐

MEDICINES

29. Have you used any **inhaled** medicines to help your breathing at any time in the last ***12 months***? NO ☒ YES ☐ ***IF NO' GO TO QUESTION 30, IF 'YES':***

What have you used in the last ***12 months***?
INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

29.1 **short acting beta-2-agonist inhalers** NO ☐ YES ☐

29.1.1 If used, how many puffs per day have you used **in the last week?** PUFFS ☐☐

29.2 **long acting beta-2-agonist inhalers** NO ☐ YES ☐

PUFFS

29.2.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

29.2.2 Is this a combination with a steroids? ☐ ☐

If YES GO TO QUESTION 29.3.2

NO YES

29.3 **inhaled steroids** **DOSE:_____** ☐ ☐

(***if combined B2 and steroid please insert inhaled steroid dose***)

PUFFS

29.3.1 If used, how many puffs per day have you used **in the last week?** ☐☐

29.3.2 If used, which one? _____ ☐☐☐

NO YES

29.4 **anti-muscarinic inhalers** ☐ ☐

PUFFS

29.4.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

30. Have you used any **pills**, **capsules**, **tablets** or **medicines**, other than inhaled medicines, to help your breathing at any time in the last ***12 months***? ☒ ☐

IF 'NO' GO TO QUESTION 31, IF 'YES':

What have you used in the last ***12 months***?

INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

NO YES

30.1 **oral methylxanthines** ☐ ☐

NO YES

30.2 **oral steroids** ☐ ☐

If used, have you used these in the last 12 months

a. More or less continuously ☐ a

b. More than 2 short courses in the last 12 months ☐ b

c. More than 1 short course in the last 12 months ☐ c

d. A single short course in the last 12 months ☐ d

e ☐ e

NO YES

30.3 **oral anti-leukotrienes** ☐ ☐

NO YES

31. **<u>In the last 5 years</u>** have you ever used inhaled steroids? ☐ ☐

IF NO GO TO QUESTION 32

YEARS

31.1. How old were you when you first started to use inhaled steroids? ☐☐

NO YES

31.2. Have you used inhaled steroids ***every year*** in the last 5 years? ☐ ☒

IF NO GO TO QUESTION 31.3, IF YES

MONTHS

31.2.1. On average how many months each year have you taken them? **2 months** ☐☐

NOW GO TO Q32

YEARS

31.3 How many of the last 5 years have you taken inhaled steroids? **Five Years** | 0 |

MONTHS

31.4. On average how many months of each of these years have you taken them? | |

USE OF HEALTH SERVICES

	NO	YES	DONT KNOW
32. Have you been vaccinated for allergy in the last 5 years? ***IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 33, IF 'YES':***	☒		
32.1 Have you been vaccinated for allergy in the last ***12 months***?			
33. In the last 5 years have you visited a hospital casualty department or emergency room because of breathing problems? ***IF NO GO TO Q34, IF YES***	☒		
33.1. Have you visited a hospital casualty department or emergency room because of breathing problems in the ***last 12 months***? ***IF NO GO TO 34, IF YES***	☒		
33.1.1 Was this due to asthma, shortness of breath or wheezing?			

33.1.2 How many times ***in the last 12 months*****?** TIMES | |

34 How many nights have you spent in hospital with any of the following conditions in the last 5 years?

	NUMBER OF NIGHTS	
a) Asthma	a	
b) Chest infection	b	
c) COPD	c	
d) Sinusitis	d	
e) Other	e	

	NO	YES
34.1 Have you spent a night in hospital in the ***last 12 months***?	☒	
35. In the last 5 years have you been seen by a doctor because of breathing problems or because of shortness of breath? ***IF NO GO TO Q36, IF YES***	☒	
35.1 Have you been seen by a general practitioner because of breathing problems or shortness of breath in the ***last 12 months? IF NO GO TO Q35.2, IF YES***	☒	

NUMBER

35.1.1 How many times? | |

	NO	YES
35.2. Have you seen a specialist (chest physician, allergy specialist, internal medicine specialist, ENT doctor) because of your breathing problems or shortness of breath ***in the last 12 months***?	☒	

NUMBER

35.4.1 How many times? | |

	M	F
36. Gender		☒

	DAY	MONTH	YEAR
37. Date of birth	07		

INTERVIEW TYPE?		**TICK ONE BOX ONLY**
a) At centre face to face	a	☒
b) At home face to face	b	
c) By telephone	c	
d) Self completed at home	d	
END FIELDWORKER NUMBER		

File 3

	NO	YES
1. Have you had wheezing or whistling in your chest at any time in the last ***12 months***?	✓	
IF 'NO' GO TO QUESTION 2, IF 'YES':		
1.1 Have you been at all breathless when the wheezing noise was present?		
1.2. Have you had this wheezing or whistling when you did ***not*** have a cold?		
2. Have you woken up with a feeling of tightness in your chest at any time in the last ***12 months***?	✓	
3. Have you had an attack of shortness of breath that came on during the day, when you were at rest, at any time in the last ***12 months***?	✓	
4. Have you had an attack of shortness of breath that came on ***following*** strenuous activity at any time in the last ***12 months***?	✓	
5. Have you been woken by an attack of shortness of breath at any time in the last ***12 months?***	✓	
IF 'NO' GO TO Q6, IF 'YES':		
5.1 Have you been woken by an attack of shortness of breath in the last ***3 months***?		
IF 'NO' GO TO Q6, IF 'YES':		
5.1.1 ***On average*** have you been woken by an attack of shortness of breath ***at least once a week*** *in the* ***last 3 months?***		
IF 'NO' GO TO Q6, IF 'YES':		
	TIMES	
5.1.1.1 How many times a week ***on average*** have you been woken by shortness of breath in the ***last 3 months***?		
6. Have you been woken by an attack of coughing at any time in the ***last 12 months***?	✓	
7. Do you ***usually*** cough first thing in the morning in the winter?	✓	
[IF DOUBTFUL, USE QUESTION 8.1 TO CONFIRM]		
8. Do you ***usually*** cough during the day, or at night, in the winter?	✓	
IF 'NO' GO TO QUESTION 9, IF 'YES':		
8.1 Do you cough like this on most days for as much as three months each year?		
9. Do you ***usually*** bring up any phlegm from your chest first thing in the morning in the winter? **[IF DOUBTFUL, USE QUESTION 10.1 TO CONFIRM]**	✓	
10.Do you ***usually*** bring up any phlegm from your chest during the day, or at night, in the winter?	✓	
'NO' GO TO QUESTION 11, IF 'YES':		
10.1 Do you bring up phlegm like this on most days for as much as three months each year?		
11. Are you disabled from walking by a condition ***other than*** heart or lung disease?	✓	

IF 'YES' STATE TYPE OF CONDITION IN THE BOX BELOW AND GO TO QUESTION 12,

IF 'NO' GO TO Q11.1:

a) bone and joint problems	a ☐
b) neurological including stroke	b ☐
c) vascular including amputations	c ☐
d) accidents	d ☐
e) other	e ☐
NOW GO TO Q12	☐

	NO	YES
11.1 Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? ***IF 'NO' GO TO QUESTION 12, IF 'YES':***	✓	☐
11.1.1 Do you get short of breath walking with other people of your own age on level ground? ***IF 'NO' GO TO QUESTION 12, IF 'YES':***	☐	☐
11.1.1.1 Do you have to stop for breath when walking at your own pace on level ground?	☐	☐
12. Have you ***ever*** had asthma? ***IF 'NO' GO TO QUESTION 13, IF 'YES':***	✓	☐
12.1 Was this confirmed by a doctor?	☐	☐

12.2 How old were you when you had your first attack of asthma? YEARS ☐☐

12.3 How old were you when you had your most recent attack of asthma? YEARS ☐☐

	NO	YES
12.4 Have you had an attack of asthma in the last ***12 months***? ***IF 'NO' GO TO 12.7, IF' YES':***	☐	☐

12.5 How many attacks of asthma have you had in the last ***12 months***? ATTACKS ☐☐
IF 'NONE', GO TO 12.7, IF 'YES':

12.6 How many attacks of asthma have you had in the last ***3 months***? ATTACKS ☐☐

12.7 How many times have you woken up because of your asthma in the last ***3 months?*** TICK ONE BOX ONLY

a) every night or almost every night	a ☐
b) more than once a week, but not most nights	b ☐
c) at least twice a month, but not more than once a week	c ☐
d) less than twice a month	d ☐
e) not at all	e ☐

12.8. How often have you had trouble with your breathing because of your asthma in the last ***3 months?*** TICK ONE BOX ONLY

a) continuously	a ☐
b) about once a day	b ☐
c) at least once a week, but less than once a day	c ☐
d) less than once a week	d ☐
e) not at all	e ☐

	NO	YES
12.9 Are you currently taking any medicines including inhalers, aerosols or tablets for asthma?	☐	☐
13. Do you have any nasal allergies, including hay fever?	☐	✓

IF 'NO' GO TO Q14, IF' YES':

	YEARS
13.1 How old were you when you first had hay fever or nasal allergy?	1 4

	NO	YES
14. Have you ***ever*** had a problem with sneezing, or a runny or a blocked nose when you did not have a cold or the flu?		✓

IF 'NO' GO TO Q17, IF 'YES':

	NO	YES
14.1. Have you had a problem with sneezing or a runny or a blocked nose when you did not have a cold or the flu ***in the last 12 months***?		✓

IF 'NO' GO TO Q15, IF' YES':

	NO	YES
14.1.1. Has this nose problem been accompanied by itchy or watery eyes?		✓

14.1.2. In which months of the year did this nose problem occur?	NO	YES
January		
February		
March		
April		
May		
June		
July		✓
August		
September		
October		
November		
December		

14.1.3. Is this set off by:	NO	YES
Grass pollen		✓
Tree pollen	✓	
Weed pollen	✓	
Moulds	✓	
Animals	✓	
Perfumes, smells or smoke	✓	
Changes in the temperature	✓	
Changes in position (such as lying down)	✓	

	NO	YES
15. ***In the last 5 years*** have you used any medication to treat problems in your nose, or hayfever?	✓	

	NO	YES
16. In the last 5 years have you ever used **nasal** steroids?	✓	

IF 'NO' GO TO QUESTION 17 IF 'YES':

	YEARS
16.1. How old were you when you first started to use **nasal** steroids?	

	NO	YES
16.2. Have you used **nasal** steroids ***every year*** in the last 5 years?		

IF 'NO' GO TO QUESTION 16.3, IF 'YES':

	MONTHS
16.2.1. On average how many months each year have you taken them?	

NOW GO TO Q17

YEARS

16.3 How many of the last 5 years have you taken **nasal** steroids? | | |

16.4. On average how many months of each of these years have you taken them? MONTHS | | |

17. In the last 5 years have you ever used **antihistamine tablets, medicines, nasal sprays or eye drops?** ***IF NO, GO TO QUESTION 18*** NO ☐ YES ☑

17.1. How old were you when you first started to use these **antihistamines**? YEARS 3 5

17.2. Have you used these **antihistamines** ***every year*** in the last 5 years? NO ☑ YES ☐
IF 'NO' GO TO QUESTION 17.3, IF'YES':

17.2.1. On average how many months each year have you taken them? MONTHS | | |
NOW GO TO Q18

17.3 How many of the last 5 years have you taken **antihistamines**? YEARS 0 1

17.4. On average how many months of each of these years have you taken them? MONTHS 0 1

18**.** Has your nose been blocked **for more than 12 weeks during the last 12 months?** NO ☑ YES ☐
IF 'NO' GO TO Q19, IF 'YES':

18.1 How old were you when you first had this symptom? YEARS | |

18.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

19. Have you had pain or pressure around the forehead, nose or eyes **for more than 12 weeks during the last 12 months?** NO ☑ YES ☐
IF 'NO' GO TO Q20, IF 'YES':

19.1 How old were you when you first had this symptom? YEARS | |

19.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

20**.** Have you had discoloured nasal discharge (snot) or discoloured mucus in the throat **for more than 12 weeks during the last 12 months?** NO ☑ YES ☐
IF 'NO' GO TO QUESTION 21, IF 'YES':

20.1 How old were you when you first had this symptom? YEARS | |

20.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

NO YES

21. Has your sense of smell been reduced or absent **for more than 12 weeks during the last 12 months?** ☑ ☐

IF 'NO' GO TO QUESTION 22, IF 'YES':

YEARS

21.1 How old were you when you first had this symptom? ☐☐

21.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

NO YES

22. Have you had mucus in your throat **for more than 12 weeks during the last 12 months**? ☑ ☐

IF 'NO' GO TO QUESTION 23, IF 'YES':

YEARS

22.1 How old were you when you first had this symptom? ☐☐

22.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

NO YES

23. Has a doctor ***ever*** told you that you have **chronic** sinusitis or nasal polyps? ☐ ☑

IF 'NO' GO TO QUESTION 24, IF 'YES':

YEARS

23.1 How old were you when you first had sinusitis OR nasal polyps? ☐☐

YEARS

23.2 How old were you when you were first diagnosed as having chronic sinusitis OR nasal polyps? ☐☐

23.3. How did your sinus problems start? TICK ONE BOX ONLY

a) Headache or pressure over the sinuses	a ☐
b) Loss of smell	b ☐
c) A common cold	c ☐
d) Frequent episodes of acute sinusitis	d ☐
e) None of the above	e ☐

23.4 If you also get asthma, how does this relate to your sinus problems? TICK ONE BOX ONLY

a) I don't get asthma	a ☐
b) Sinusitis usually comes before the asthma worsens	b ☐
c) Asthma usually comes before the sinusitis worsens	c ☐
d) Both usually start with a common cold	d ☐

e) None of the above e ☐

23.5 If you drink alcohol does this worsen your sinus problems? NO ☐ YES ☐ N/A ☐

23.5.1 - 4 ***IF 'NO' or N/A, skip to 23.6 ; IF 'YES', which symptoms does alcohol affect?***

	NO	YES
23.5.1 Blocked Nose	☐	☐
23.5.2 Runny Nose	☐	☐
23.5.3 Post nasal drip (mucus in the throat)	☐	☐
23.5.4 Sneezing	☐	☐

23.6 Have you ***ever*** had surgery for nasal/sinus problems? NO ☐ YES ☐

23.7. In the last 5 years have you ever used **antibiotics for nasal/sinus problems**? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 24

23.8. How old were you when you first started to use **antibiotics for nasal/sinus problems**? YEARS ☐☐

23.9. Have you used **antibiotics for nasal/sinus problems *every year*** in the last 5 years? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 23.10, IF 'YES':

23.9.1. On average how many months each year have you taken them? MONTHS ☐☐
NOW GO TO Q24

23.10 How many of the last 5 years have you taken **antibiotics for nasal/sinus problems**? YEARS ☐☐

23.11. On average how many months of each of these years have you taken them? MONTHS ☐☐

24. Have you ***ever*** had eczema or any kind of skin allergy? NO ☐ YES ✓
IF 'NO' GO TO Q25, IF 'YES':

24.1. Was this problem ***ever*** associated with your work? NO ✓ YES ☐
IF 'NO' GO TO QUESTION 25, IF 'YES':

24.2. What job were you doing that made it worse? ☐☐☐☐
_____

24.3. Do you know what caused the problem at work? NO ☐ YES ☐
IF 'YES' What was this problem?_____

25. Have you ***ever*** had an itchy rash that was coming and going for at ***least 6 months***? NO ✓ YES ☐
IF 'NO' GO TO QUESTION 26, IF 'YES':

25.1. Have you had this itchy rash ***in the last 12 months?*** NO ☐ YES ☐
IF 'NO' GO TO QUESTION 26, IF 'YES':

25.1.1. Has this itchy rash ***at any time*** affected any of the following places: the folds of the elbows, behind the knees, in front of the ankles under the buttocks or around the neck, ears or eyes? NO ☐ YES ☐

25.1.2. Does this itchy rash affect your hands? NO ☐ YES ☐

	NO	YES
26. Have you ***ever*** had any difficulty with your breathing after taking medicines?	✓	

IF 'NO' GO TO QUESTION 27 IF 'YES':

26.1 Which medicines? _____ 26.1.1 26.1.2

	NO	YES
27. Have you ***ever*** had a runny or a stuffy nose or sneezing after taking medicines?	✓	

IF 'NO' GO TO QUESTION 28, IF 'YES':

27.1 Which medicines? _____ 27.1.1 27.1.2

	NO	YES
28. Have you ***ever*** had uticaria, nettle rash or hives after taking medicines?	✓	

IF 'NO' GO TO QUESTION 29, IF 'YES':

28.1 Which medicines? _____ 28.1.1 28.1.2

	NO	YES
29. Have you ***ever*** had an illness or trouble caused by eating a ***particular*** food or foods?		✓

IF 'YES' GO TO QUESTION 29.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

	NO	YES
29.1 Have you nearly always had the same illness or trouble after eating this type of food?	✓	

IF 'YES' GO TO QUESTION 29.1.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

29.1.1 What type of food was this? [List up to 3]

CELERY _____ 29.1.1.1	2	4
_____ 29.1.1.2		
_____ 29.1.1.3		

29.1.2 Did this illness or trouble include:

	NO	YES
29.1.2.1. Itching, tingling or swelling in the mouth, lips or throat?	✓	
29.1.2.2. A rash, nettle sting like rash or itchy skin?	✓	
29.1.2.3. Diarrhoea or vomiting (other than food poisoning)?	✓	
29.1.2.4. Runny or stuffy nose?	✓	
29.1.2.5. Red, sore or running eyes?	✓	
29.1.2.6. Difficulty swallowing?	✓	
29.1.2.7. Breathlessness?	✓	
29.1.2.8. Stiffness in your joints?	✓	
29.1.2.9. Fainting or dizziness?	✓	
29.1.2.10. Headaches?		✓

SOME FURTHER QUESTIONS

1. How old was your mother when you were born? — YEARS: 2 5

2. Were you hospitalised before the age of two years for lung disease? — NO ✓ / YES

Your parents' smoking

3. Did your father ***ever*** smoke regularly during your childhood? — NO ✓ / YES / DON'T KNOW

4. Did your mother ***ever*** smoke regularly during your childhood, or before you were born? — NO ✓ / YES / DON'T KNOW

IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 5, IF 'YES':

4.1 When your mother was pregnant, in particular with you, did she: — TICK ONE BOX ONLY

a) Stop smoking before pregnancy? — a
b) Cut down or stop during pregnancy? — b
c) Smoke as usual during pregnancy? — c
d) Don't know — d

5. What country were you born in? SWEDEN — 2 0 1

6. How many brothers do or did you have? — NUMBER: 0 2

IF 'NONE' GO TO QUESTION 7, IF 'ONE OR MORE':

NUMBER

6.1 How many ***older*** brothers? — 0 0
6.2 How many ***younger*** brothers? — 0 2
6.3 How many of your brothers ever had asthma? — 0 1

6.4 How many of your ***other*** brothers ever had eczema, skin or nasal allergy or hay fever? — NUMBER: 0 1

7. How many sisters do or did you have? — NUMBER: 0 0

IF 'NONE' GO TO QUESTION 8, IF 'ONE OR MORE':

NUMBER

7.1 How many ***older*** sisters?
7.2 How many ***younger*** sisters?
7.3 How many of your sisters ever had asthma?
7.4 How many of your ***other*** sisters ever had eczema, skin or nasal allergy or hay fever?

8. Did your mother ***ever*** have asthma? — NO ✓ / YES / DON'T KNOW

9. Did your mother ***ever*** have eczema, skin or nasal allergy or hay fever? — NO ✓ / YES / DON'T KNOW

10. Did your father ***ever*** have asthma? — NO ✓ / YES / DON'T KNOW

	NO	YES	DON'T KNOW
11. Did your father ***ever*** have eczema, skin or nasal allergy or hay fever?	✓		
12. Did you regularly share your bedroom with any ***older*** children before the age of five years?	✓		
13. Did you go to a school, play-school or nursery with ***older*** children before the age of five years?		✓	
14. Did you have a serious respiratory infection before the age of five years?	✓		

	NO	YES	DONT KNOW
15. Was there a dog in your home?			
15.1 During your first year of life	✓		
15.2 When you were aged 1 to 4 years	✓		
15.3 When you were aged 5-15 years	✓		
16. Was there a cat in your home?			
16.1. During your first year of life	✓		
16.2 When you were aged 1 to 4 years	✓		
16.3 When you were aged 5-15 years	✓		

17. What term best describes the place you lived most of the time when you were under the age of five years?

	TICK ONE BOX ONLY	
a) Farm	a	
b) Village in a rural area	b	
c) Small town	c	✓
d) Suburb of a city	d	
e) Inner city	e	

WORK AND EDUCATION

	NO	YES
18. Are you a full time student?	✓	

IF 'YES' GO TO QUESTION 21, IF 'NO':

	YEARS
18.1 At what age did you complete full time education?	2 2

I would now like to ask you some questions on the type of jobs that you have done.

18.2. Are you currently:	TICK ONE BOX ONLY	
Employed (including military service)	1	✓
Self employed	2	
Unemployed, looking for work	3	
Not working because of poor health	4	
Full-time house-person	5	
Full time student	6	
Retired	7	
Other	8	

NO YES

18.3 Have you ***ever*** had a job for more than three consecutive months? [ ] [✓]

IF 'NO' GO TO Q22, IF 'YES':

YEARS

18.4 How old were you when you started your first job? [2][3]

18.5. What was this first job? (*be as precise as possible*) [4][1][1][3]

DATA ENTRY_____

NO YES

18.6. Would you say that allergies or breathing problems influenced your **initial** job choice? [✓] [ ]

NO YES

18.7. Would you say that allergies or breathing problems are likely to influence your **future** job choices? [✓] [ ]

NO YES

18.8. Are you currently still working in your first job (as in question 18.4)? [✓] [ ]

IF 'YE'S, GO TO Q18.11, IF 'NO':

18.9 What is your current or most recent job? [Be as precise as possible, if not working, please complete as Not Working]

STATISTICIAN_____ [3][4][3][4]

YEARS

18.10 How old were you when you started working in this job? [2][5]

18.11 In this job were you: TICK ONE BOX ONLY

a) A manager working for an employer? a [ ]
b) A foreman or supervisor working for an employer? b [ ]
c) Working for an employer, but neither a manager, supervisor or foreman? c [✓]
d) Self-employed? d [ ]

NO YES

19. Does or did being at work ever make your chest tight or wheezy? [✓] [ ]

NO YES

19.1 Is or was your breathing better at weekends or holidays? [✓] [ ]

DAYS

20. How many days of work have you lost because of asthma, shortness of breath or wheezing in the last **12 months?** [**0**][**0**][**0**]

NO YES

21. Have you ever worked in a job which exposed you to vapours, gas, dust or fumes? [✓] [ ]

IF 'NO' GO TO QUESTION 22, IF 'YES':

21.1 What was or is this job? [Be as precise as possible] I*f current job write 'current job'* [ ][ ][ ][ ]

_____

NO YES

22. Have you ever been involved in an incident at home, work or elsewhere that exposed you to high levels of vapours, gases or fumes? [✓] [ ]

IF NO GO TO Q23; IF YES:

22.1 When did this happen?

a) Less than a year ago a [ ]
b) Between one and five years ago b [ ]
c) More than five years ago c [ ]

22.2 Could you classify this incident as:

a) A fire or an explosion — a ☐
b) A leak or a spill — b ☐
c) (Mixing of) cleaning products — c ☐
d) Something else:_____ — d ☐

22.3 Where did this happen?

a) In your own home — a ☐
b) In your workplace — b ☐
c) Somewhere else indoors — c ☐
d) Outdoors — d ☐

22.4 Did you experience respiratory symptoms within 24 hours following this incident? — NO ☐ YES ☐

23. Have you ever had to change or leave your job because it affected your breathing? — NO ✓ YES ☐

IF 'NO' GO TO QUESTION 24 IF 'YES':

23.1 What was this job? [Be as precise as possible]

_____ ☐☐☐☐

ENVIRONMENT

24. How often do cars pass your house? — TICK ONE BOX ONLY

a) More than 80 per hour — a ☐
b) between 21and 80 per hour — b ☐
c) between 5 and 20 per hour — c ✓
d) less than 5 per hour — d ☐

25. How often do heavy vehicles (e.g. trucks/buses) pass your house? — TICK ONE BOX ONLY

a) More than 20 per hour — a ☐
b) between 4 and 20 per hour — b ☐
c) at least one but less than 4 per hour — c ☐
d) less than one per hour — d ✓

TOBACCO AND ALCOHOL

26. Have you ever smoked for as long as a year? — NO ✓ YES ☐

['YES' means at least 20 packs of cigarettes or 12 oz (360 grams) of tobacco in a lifetime, or at least one cigarette per day or one cigar a week for one year]
IF 'NO' GO TO QUESTION 27, IF 'YES':

26.1 How old were you when you started smoking? — YEARS ☐☐

26.2 Do you **now** smoke, as of ***one month ago***? — NO ☐ YES ☐

***IF 'NO' GO TO QUESTION 26.3, IF 'YES'*:**

NUMBER

26.2.1-4 How much do you ***now*** smoke on average

26.2.1 number of cigarettes ***per day*** ☐☐
26.2.2 number of cigarillos ***per day*** ☐☐
26.2.3 number of cigars ***a week*** ☐☐
26.2.4 pipe tobacco in a) ounces / ***week*** ☐☐
b) grams / ***week*** ☐☐☐

NO YES

26.3 Have you stopped or cut down smoking? ☐☐

IF 'NO' GO TO QUESTION 26.4, IF 'YES':

YEARS

26.3.1 How old were you when you stopped or cut down smoking? ☐☐

26.3.2. 1-4 ***on average*** of the entire time you smoked, before you stopped or cut down, how much did you smoke?

NUMBER

26.3.2.1 number of cigarettes per day	☐☐
26.3.2.2 number of cigarillos per day	☐☐
26.3.2.3 number of cigars a week	☐☐
26.3.2.4 pipe tobacco in a) ounces / week	☐☐
b) grams / week	☐☐☐

NO YES

26.4 Do you or did you inhale the smoke? ☐ ☐

NO YES

27. Have you been **regularly** exposed to tobacco smoke in the last ***12months***? ✓ ☐

['Regularly' means on most days or nights]

IF 'NO' GO TO QUESTION 28, IF 'YES':

NUMBER

27.1 Not counting yourself, how many people in your household smoke regularly? ☐☐

NO YES

27.2 Do people smoke regularly in the room where you work? ☐ ☐

HOURS

27.3 How many hours per day are you exposed to ***other people's*** tobacco smoke? ☐☐

Please provide more information.

27.7 On average how many hours per day, are you exposed to other peoples tobacco smoke In the following locations

NUMBER

a) At home	a	☐☐
b) At workplace	b	☐☐
c) In bars, restaurants, cinemas or similar social settings	c	☐☐
d) Elsewhere	d	☐☐

28. How many units of alcohol do you drink daily/weekly?

(one unit = one small bottle of beer (250 ml), a small glass of red or white wine (120 ml) or one shot of spirits (40ml))

TICK ONE BOX ONLY

a) Never	a	☐
b) Less than one a week	b	☐
c) At least one a week but less than one a day	c	☐
d) 1-3 units a day	d	✓
e) 4 units a day	e	☐
f) More than 5 units per day	f	☐

<u>MEDICINES</u>

NO YES

29. Have you used any **inhaled** medicines to help your breathing at any time in the last ***12 months***? ☒ ☐

IF NO' GO TO QUESTION 30, IF 'YES':

What have you used in the last ***12 months***?

INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

NO YES

29.1 **short acting beta-2-agonist inhalers** ☐ ☐

PUFFS

29.1.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

29.2 **long acting beta-2-agonist inhalers** ☐ ☐

PUFFS

29.2.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

29.2.2 Is this a combination with a steroids? ☐ ☐

If YES GO TO QUESTION 29.3.2

NO YES

29.3 **inhaled steroids** **DOSE:_____** ☐ ☐

(***if combined B2 and steroid please insert inhaled steroid dose***)

PUFFS

29.3.1 If used, how many puffs per day have you used **in the last week?** ☐☐

29.3.2 If used, which one? _____ ☐☐☐

NO YES

29.4 **anti-muscarinic inhalers** ☐ ☐

PUFFS

29.4.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

30. Have you used any **pills**, **capsules**, **tablets** or **medicines**, other than inhaled medicines, to help your breathing at any time in the last ***12 months***? ✓ ☐

IF 'NO' GO TO QUESTION 31, IF 'YES':

What have you used in the last ***12 months***?

INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

NO YES

30.1 **oral methylxanthines** ☐ ☐

NO YES

30.2 **oral steroids** ☐ ☐

If used, have you used these in the last 12 months a

a. More or less continuously ☐ b

b. More than 2 short courses in the last 12 months ☐ c

c. More than 1 short course in the last 12 months ☐ d

d. A single short course in the last 12 months ☐ e

NO YES

30.3 **oral anti-leukotrienes** ☐ ☐

NO YES

31. **<u>In the last 5 years</u>** have you ever used inhaled steroids? ✓ ☐

IF NO GO TO QUESTION 32

YEARS

31.1. How old were you when you first started to use inhaled steroids? ☐☐

NO YES

31.2. Have you used inhaled steroids ***every year*** in the last 5 years? ☐ ☐

IF NO GO TO QUESTION 31.3, IF YES

MONTHS

31.2.1. On average how many months each year have you taken them? ☐☐
NOW GO TO Q32

YEARS

31.3 How many of the last 5 years have you taken inhaled steroids? ☐☐

MONTHS

31.4. On average how many months of each of these years have you taken them? ☐☐

USE OF HEALTH SERVICES

	NO	YES	DONT KNOW
32. Have you been vaccinated for allergy in the last 5 years?	✓		

IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 33, IF 'YES':

	NO	YES
32.1 Have you been vaccinated for allergy in the last ***12 months***?		

	NO	YES
33. In the last 5 years have you visited a hospital casualty department or emergency room because of breathing problems? ***IF NO GO TO Q34, IF YES***	✓	

	NO	YES
33.1. Have you visited a hospital casualty department or emergency room because of breathing problems in the ***last 12 months***? ***IF NO GO TO 34, IF YES***		

	NO	YES
33.1.1 Was this due to asthma, shortness of breath or wheezing?		

TIMES

33.1.2 How many times ***in the last 12 months*****?** ☐☐

34 How many nights have you spent in hospital with any of the following conditions in the last 5 years?

	NUMBER OF NIGHTS	
a) Asthma	a	0 0
b) Chest infection	b	0 0
c) COPD	c	0 0
d) Sinusitis	d	0 0
e) Other	e	0 0

	NO	YES
34.1 Have you spent a night in hospital in the ***last 12 months***?	✓	

	NO	YES
35. In the last 5 years have you been seen by a doctor because of breathing problems or because of shortness of breath? ***IF NO GO TO Q36, IF YES***	✓	

	NO	YES
35.1 Have you been seen by a general practitioner because of breathing problems or shortness of breath in the ***last 12 months? IF NO GO TO Q35.2, IF YES***	✓	

NUMBER

35.1.1 How many times? ☐☐

	NO	YES
35.2. Have you seen a specialist (chest physician, allergy specialist, internal medicine specialist, ENT doctor) because of your breathing problems or shortness of breath ***in the last 12 months***?	✓	

NUMBER

35.4.1 How many times? | | |

	M	F
36. Gender	✓	

	DAY	MONTH	YEAR
37. Date of birth	2 5	0 6	7 3

INTERVIEW TYPE? **TICK ONE BOX ONLY**		
a) At centre face to face	a	✓
b) At home face to face	b	
c) By telephone	c	
d) Self completed at home	d	
END FIELDWORKER NUMBER		2

File 4

1. Have you had wheezing or whistling in your chest at any time in the last ***12 months***? NO ☒ YES ☐
IF 'NO' GO TO QUESTION 2, IF 'YES':

1.1 Have you been at all breathless when the wheezing noise was present? NO ☐ YES ☐

1.2. Have you had this wheezing or whistling when you did ***not*** have a cold? NO ☐ YES ☐

2. Have you woken up with a feeling of tightness in your chest at any time in the last ***12 months***? NO ☒ YES ☐

3. Have you had an attack of shortness of breath that came on during the day, when you were at rest, at any time in the last ***12 months***? NO ☒ YES ☐

4. Have you had an attack of shortness of breath that came on ***following*** strenuous activity at any time in the last ***12 months***? NO ☒ YES ☐

5. Have you been woken by an attack of shortness of breath at any time in the last ***12 months?*** NO ☒ YES ☐
IF 'NO' GO TO Q6, IF 'YES':

5.1 Have you been woken by an attack of shortness of breath in the last ***3 months***? NO ☐ YES ☐
IF 'NO' GO TO Q6, IF 'YES':

5.1.1 ***On average*** have you been woken by an attack of shortness of breath ***at least once a week*** *in the* ***last 3 months?*** NO ☐ YES ☐
IF 'NO' GO TO Q6, IF 'YES':

5.1.1.1 How many times a week ***on average*** have you been woken by shortness of breath in the ***last 3 months***? TIMES ☐☐

6. Have you been woken by an attack of coughing at any time in the ***last 12 months***? NO ☐ YES ☒

7. Do you ***usually*** cough first thing in the morning in the winter? NO ☒ YES ☐
[IF DOUBTFUL, USE QUESTION 8.1 TO CONFIRM]

8. Do you ***usually*** cough during the day, or at night, in the winter? NO ☒ YES ☐
IF 'NO' GO TO QUESTION 9, IF 'YES':

8.1 Do you cough like this on most days for as much as three months each year? NO ☐ YES ☐

9. Do you ***usually*** bring up any phlegm from your chest first thing in the morning in the winter? **[IF DOUBTFUL, USE QUESTION 10.1 TO CONFIRM]** NO ☒ YES ☐

10.Do you ***usually*** bring up any phlegm from your chest during the day, or at night, in the winter? NO ☒ YES ☐
'NO' GO TO QUESTION 11, IF 'YES':

10.1 Do you bring up phlegm like this on most days for as much as three months each year? NO ☐ YES ☐

NO YES

11. Are you disabled from walking by a condition ***other than*** heart or lung disease? ☐ ☒

IF 'YES' STATE TYPE OF CONDITION IN THE BOX BELOW AND GO TO QUESTION 12, IF 'NO' GO TO Q11.1:

a) bone and joint problems	a ☒
b) neurological including stroke	b ☐
c) vascular including amputations	c ☐
d) accidents	d ☐
e) other	e ☐
NOW GO TO Q12	☐

NO YES

11.1 Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? ☐ ☒

IF 'NO' GO TO QUESTION 12, IF 'YES':

NO YES

11.1.1 Do you get short of breath walking with other people of your own age on level ground? ☒ ☐

IF 'NO' GO TO QUESTION 12, IF 'YES':

NO YES

11.1.1.1 Do you have to stop for breath when walking at your own pace on level ground? ☐ ☐

NO YES

12. Have you ***ever*** had asthma? ☐ ☒

IF 'NO' GO TO QUESTION 13, IF 'YES':

NO YES

12.1 Was this confirmed by a doctor? ☐ ☒

YEARS

12.2 How old were you when you had your first attack of asthma? 0 0 9

YEARS

12.3 How old were you when you had your most recent attack of asthma? 1 9

NO YES

12.4 Have you had an attack of asthma in the last ***12 months***? ☒ ☐

IF 'NO' GO TO 12.7, IF' YES':

ATTACKS

12.5 How many attacks of asthma have you had in the last ***12 months***? ☐☐

IF 'NONE', GO TO 12.7, IF 'YES':

ATTACKS

12.6 How many attacks of asthma have you had in the last ***3 months***? ☐☐

12.7 How many times have you woken up because of your asthma in the last ***3 months?*** TICK ONE BOX ONLY

a) every night or almost every night	a ☐
b) more than once a week, but not most nights	b ☐
c) at least twice a month, but not more than once a week	c ☐
d) less than twice a month	d ☐
e) not at all	e ☒

12.8. How often have you had trouble with your breathing because of your asthma in the last ***3 months?*** TICK ONE BOX ONLY

a) continuously	a ☐
b) about once a day	b ☐
c) at least once a week, but less than once a day	c ☐
d) less than once a week	d ☒
e) not at all	e ☐

NO YES

12.9 Are you currently taking any medicines including inhalers, aerosols or tablets for ☒ ☐

asthma?

13. Do you have any nasal allergies, including hay fever? NO ☐ YES ☒

IF 'NO' GO TO Q14, IF' YES':

13.1 How old were you when you first had hay fever or nasal allergy? YEARS 0 8

14. Have you ***ever*** had a problem with sneezing, or a runny or a blocked nose when you did not have a cold or the flu? NO ☐ YES ☒

IF 'NO' GO TO Q17, IF 'YES':

14.1. Have you had a problem with sneezing or a runny or a blocked nose when you did not have a cold or the flu ***in the last 12 months***? NO ☐ YES ☒

IF 'NO' GO TO Q15, IF' YES':

14.1.1. Has this nose problem been accompanied by itchy or watery eyes? NO ☐ YES ☒

14.1.2. In which months of the year did this nose problem occur?

	NO	YES
January	☐	☒
February	☐	☒
March	☐	☒
April	☐	☒
May	☐	☒
June	☐	☒
July	☐	☒
August	☐	☒
September	☐	☒
October	☐	☒
November	☐	☒
December	☐	☒

14.1.3. Is this set off by:

	NO	YES
Grass pollen	☐	☒
Tree pollen	☒	☐
Weed pollen	☒	☐
Moulds	☒	☐
Animals	☒	☐
Perfumes, smells or smoke	☒	☐
Changes in the temperature	☒	☐
Changes in position (such as lying down)	☒	☐

15. ***In the last 5 years*** have you used any medication to treat problems in your nose, or hayfever? NO ☒ YES ☐

16. In the last 5 years have you ever used **nasal** steroids? NO ☒ YES ☐

IF 'NO' GO TO QUESTION 17 IF 'YES':

16.1. How old were you when you first started to use **nasal** steroids? YEARS ☐☐

16.2. Have you used **nasal** steroids ***every year*** in the last 5 years? NO ☐ YES ☐

IF 'NO' GO TO QUESTION 16.3, IF 'YES':

16.2.1. On average how many months each year have you taken them? MONTHS ☐☐

NOW GO TO Q17

16.3 How many of the last 5 years have you taken **nasal** steroids?

YEARS

16.4. On average how many months of each of these years have you taken them?

MONTHS

17. In the last 5 years have you ever used **antihistamine tablets, medicines, nasal sprays or eye drops?** ***IF NO, GO TO QUESTION 18***

NO	YES
	☒

17.1. How old were you when you first started to use these **antihistamines**?

YEARS

1	9

17.2. Have you used these **antihistamines** ***every year*** in the last 5 years?
IF 'NO' GO TO QUESTION 17.3, IF'YES':

NO	YES
☒	

17.2.1. On average how many months each year have you taken them?
NOW GO TO Q18

MONTHS

17.3 How many of the last 5 years have you taken **antihistamines**?

YEARS

0	2

17.4. On average how many months of each of these years have you taken them?

MONTHS

0	4

18**.** Has your nose been blocked **for more than 12 weeks during the last 12 months?**
IF 'NO' GO TO Q19, IF 'YES':

NO	YES
☒	

18.1 How old were you when you first had this symptom?

YEARS

18.2 How often have you had this symptom in the last month?

TICK ONE BOX ONLY

a) Not at all	a
b) Less than once a week	b
c) At least once a week, but less than once a day	c
d) About once a day	d
e) Continuously	e

19. Have you had pain or pressure around the forehead, nose or eyes **for more than 12 weeks during the last 12 months?**
IF 'NO' GO TO Q20, IF 'YES':

NO	YES
	☒

19.1 How old were you when you first had this symptom?

YEARS

3	4

19.2 How often have you had this symptom in the last month?

TICK ONE BOX ONLY

a) Not at all	a
b) Less than once a week	b ☒
c) At least once a week, but less than once a day	c
d) About once a day	d
e) Continuously	e

20**.** Have you had discoloured nasal discharge (snot) or discoloured mucus in the throat **for more than 12 weeks during the last 12 months?**
IF 'NO' GO TO QUESTION 21, IF 'YES':

NO	YES
☒	

20.1 How old were you when you first had this symptom?

YEARS

20.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

21. Has your sense of smell been reduced or absent **for more than 12 weeks during the last 12 months?** NO ☒ YES ☐

IF 'NO' GO TO QUESTION 22, IF 'YES':

21.1 How old were you when you first had this symptom? YEARS ☐☐

21.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

22. Have you had mucus in your throat **for more than 12 weeks during the last 12 months**? NO ☒ YES ☐

IF 'NO' GO TO QUESTION 23, IF 'YES':

22.1 How old were you when you first had this symptom? YEARS ☐☐

22.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

23. Has a doctor ***ever*** told you that you have **chronic** sinusitis or nasal polyps? NO ☐ YES ☒

IF 'NO' GO TO QUESTION 24, IF 'YES':

23.1 How old were you when you first had sinusitis OR nasal polyps? YEARS 3 5

23.2 How old were you when you were first diagnosed as having chronic sinusitis OR nasal polyps? YEARS 3 5

23.3. How did your sinus problems start? TICK ONE BOX ONLY

a) Headache or pressure over the sinuses	a ☒
b) Loss of smell	b ☐
c) A common cold	c ☐
d) Frequent episodes of acute sinusitis	d ☐
e) None of the above	e ☐

23.4 If you also get asthma, how does this relate to your sinus problems? TICK ONE BOX ONLY

a) I don't get asthma	a ☒
b) Sinusitis usually comes before the asthma worsens	b ☐
c) Asthma usually comes before the sinusitis worsens	c ☐
d) Both usually start with a common cold	d ☐

e) None of the above — e ☐

23.5 If you drink alcohol does this worsen your sinus problems? NO ☒ YES ☐ N/A ☐

23.5.1 - 4 ***IF 'NO' or N/A, skip to 23.6 ; IF 'YES', which symptoms does alcohol affect?***

	NO	YES
23.5.1 Blocked Nose	☐	☐
23.5.2 Runny Nose	☐	☐
23.5.3 Post nasal drip (mucus in the throat)	☐	☐
23.5.4 Sneezing	☐	☐

23.6 Have you ***ever*** had surgery for nasal/sinus problems? NO ☒ YES ☐

23.7. In the last 5 years have you ever used **antibiotics for nasal/sinus problems**? NO ☐ YES ☒
IF 'NO' GO TO QUESTION 24

23.8. How old were you when you first started to use **antibiotics for nasal/sinus problems**? YEARS 3 5

23.9. Have you used **antibiotics for nasal/sinus problems *every year*** in the last 5 years? NO ☒ YES ☐
IF 'NO' GO TO QUESTION 23.10, IF 'YES':

23.9.1. On average how many months each year have you taken them? MONTHS 1 0
NOW GO TO Q24

23.10 How many of the last 5 years have you taken **antibiotics for nasal/sinus problems**? YEARS ☐☐

23.11. On average how many months of each of these years have you taken them? MONTHS ☐☐

24. Have you ***ever*** had eczema or any kind of skin allergy? NO ☒ YES ☐
IF 'NO' GO TO Q25, IF 'YES':

24.1. Was this problem ***ever*** associated with your work? NO ☐ YES ☐
IF 'NO' GO TO QUESTION 25, IF 'YES':

24.2. What job were you doing that made it worse? ☐☐☐☐
_____

24.3. Do you know what caused the problem at work? NO ☐ YES ☐
IF 'YES' What was this problem?_____

25. Have you ***ever*** had an itchy rash that was coming and going for at ***least 6 months***? NO ☒ YES ☐
IF 'NO' GO TO QUESTION 26, IF 'YES':

25.1. Have you had this itchy rash ***in the last 12 months?*** NO ☐ YES ☐
IF 'NO' GO TO QUESTION 26, IF 'YES':

25.1.1. Has this itchy rash ***at any time*** affected any of the following places: the folds of the elbows, behind the knees, in front of the ankles under the buttocks or around the neck, ears or eyes? NO ☐ YES ☐

25.1.2. Does this itchy rash affect your hands? NO ☐ YES ☐

NO YES

26. Have you ***ever*** had any difficulty with your breathing after taking medicines? ☒ ☐

IF 'NO' GO TO QUESTION 27 IF 'YES':

26.1 Which medicines? _____ 26.1.1 ☐
26.1.2 ☐

NO YES

27. Have you ***ever*** had a runny or a stuffy nose or sneezing after taking medicines? ☒ ☐

IF 'NO' GO TO QUESTION 28, IF 'YES':

27.1 Which medicines? _____ 27.1.1 ☐
27.1.2 ☐

NO YES

28. Have you ***ever*** had uticaria, nettle rash or hives after taking medicines? ☒ ☐

IF 'NO' GO TO QUESTION 29, IF 'YES':

28.1 Which medicines? _____ 28.1.1 ☐
28.1.2 ☐

NO YES

29. Have you ***ever*** had an illness or trouble caused by eating a ***particular*** food or foods? ☒ ☐

IF 'YES' GO TO QUESTION 29.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

NO YES

29.1 Have you nearly always had the same illness or trouble after eating this type of food? ☐ ☐

IF 'YES' GO TO QUESTION 29.1.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

29.1.1 What type of food was this? [List up to 3]

_____29.1.1.1 ☐☐
_____29.1.1.2 ☐☐
_____29.1.1.3 ☐☐

29.1.2 Did this illness or trouble include:

	NO	YES
29.1.2.1. Itching, tingling or swelling in the mouth, lips or throat?	☐	☐
29.1.2.2. A rash, nettle sting like rash or itchy skin?	☐	☐
29.1.2.3. Diarrhoea or vomiting (other than food poisoning)?	☐	☐
29.1.2.4. Runny or stuffy nose?	☐	☐
29.1.2.5. Red, sore or running eyes?	☐	☐
29.1.2.6. Difficulty swallowing?	☐	☐
29.1.2.7. Breathlessness?	☐	☐
29.1.2.8. Stiffness in your joints?	☐	☐
29.1.2.9. Fainting or dizziness?	☐	☐
29.1.2.10. Headaches?	☐	☐

SOME FURTHER QUESTIONS

1. How old was your mother when you were born? — YEARS: 18

2. Were you hospitalised before the age of two years for lung disease? — NO ☒ YES ☐

Your parents' smoking

3. Did your father ***ever*** smoke regularly during your childhood? — NO ☒ YES ☐ DON'T KNOW ☐

4. Did your mother ***ever*** smoke regularly during your childhood, or before you were born? — NO ☒ YES ☐ DON'T KNOW ☐

IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 5, IF 'YES':

4.1 When your mother was pregnant, in particular with you, did she: — TICK ONE BOX ONLY

a) Stop smoking before pregnancy? a ☐
b) Cut down or stop during pregnancy? b ☐
c) Smoke as usual during pregnancy? c ☐
d) Don't know d ☐

5. What country were you born in? _____ ☐☐☐

6. How many brothers do or did you have? — NUMBER: 01
IF 'NONE' GO TO QUESTION 7, IF 'ONE OR MORE':

NUMBER

6.1 How many ***older*** brothers? 0
6.2 How many ***younger*** brothers? 1
6.3 How many of your brothers ever had asthma? 0

6.4 How many of your ***other*** brothers ever had eczema, skin or nasal allergy or hay fever? — NUMBER: 0

7. How many sisters do or did you have? — NUMBER: 0
IF 'NONE' GO TO QUESTION 8, IF 'ONE OR MORE':

NUMBER

7.1 How many ***older*** sisters? ☐☐
7.2 How many ***younger*** sisters? ☐☐
7.3 How many of your sisters ever had asthma? ☐☐
7.4 How many of your ***other*** sisters ever had eczema, skin or nasal allergy or hay fever? ☐☐

8. Did your mother ***ever*** have asthma? — NO ☒ YES ☐ DON'T KNOW ☐

9. Did your mother ***ever*** have eczema, skin or nasal allergy or hay fever? — NO ☐ YES ☒ DON'T KNOW ☐

10. Did your father ***ever*** have asthma? — NO ☒ YES ☐ DON'T KNOW ☐

	NO	YES	DON'T KNOW
11. Did your father ***ever*** have eczema, skin or nasal allergy or hay fever?	☒	☐	☐
12. Did you regularly share your bedroom with any ***older*** children before the age of five years?	☒	☐	☐
13. Did you go to a school, play-school or nursery with ***older*** children before the age of five years?	☒	☐	☐
14. Did you have a serious respiratory infection before the age of five years?	☐	☐	☒

	NO	YES	DONT KNOW
15. Was there a dog in your home?			
15.1 During your first year of life	☐	☒	☐
15.2 When you were aged 1 to 4 years	☒	☐	☐
15.3 When you were aged 5-15 years	☒	☐	☐

	NO	YES	DONT KNOW
16. Was there a cat in your home?			
16.1. During your first year of life	☒	☐	☐
16.2 When you were aged 1 to 4 years	☒	☐	☐
16.3 When you were aged 5-15 years	☒	☐	☐

17. What term best describes the place you lived most of the time when you were under the age of five years?

	TICK ONE BOX ONLY	
a) Farm	a	☒
b) Village in a rural area	b	☐
c) Small town	c	☐
d) Suburb of a city	d	☐
e) Inner city	e	☐

WORK AND EDUCATION

	NO	YES
18. Are you a full time student?	☒	☐

IF 'YES' GO TO QUESTION 21, IF 'NO':

	YEARS
18.1 At what age did you complete full time education?	☐☐

I would now like to ask you some questions on the type of jobs that you have done.

18.2. Are you currently:	TICK ONE BOX ONLY	
Employed (including military service)	1	☒
Self employed	2	☐
Unemployed, looking for work	3	☐
Not working because of poor health	4	☐
Full-time house-person	5	☐
Full time student	6	☐
Retired	7	☐
Other	8	☐

	NO	YES
18.3 Have you ***ever*** had a job for more than <u>three consecutive months</u>?	☐	☒

IF 'NO' GO TO Q22, IF 'YES':

18.4 How old were you when you started your first job? YEARS [2][4]

18.5. What was this first job? (*be as precise as possible*) [ ][ ][ ][ ]

_____

18.6. Would you say that allergies or breathing problems influenced your **initial** job choice? NO [X] YES [ ]

18.7. Would you say that allergies or breathing problems are likely to influence your **future** job choices? NO [X] YES [ ]

18.8. Are you currently still working in your first job (as in question 18.4)? NO [ ] YES [X]

IF 'YE'S, GO TO Q18.11, IF 'NO':

18.9 What is your current or most recent job? [Be as precise as possible, if not working, please complete as Not Working]

_____ [ ][ ][ ][ ]

18.10 How old were you when you started working in this job? YEARS [ ][ ]

18.11 In this job were you: TICK ONE BOX ONLY

a) A manager working for an employer? a [X]
b) A foreman or supervisor working for an employer? b [ ]
c) Working for an employer, but neither a manager, supervisor or foreman? c [ ]
d) Self-employed? d [ ]

19. Does or did being at work ever make your chest tight or wheezy? NO [X] YES [ ]

19.1 Is or was your breathing better at weekends or holidays? NO [ ] YES [ ]

20. How many days of work have you lost because of asthma, shortness of breath or wheezing in the last **12 months?** DAYS none [**1**][**2**][**3**]

21. Have you ever worked in a job which exposed you to vapours, gas, dust or fumes? NO [X] YES [ ]

IF 'NO' GO TO QUESTION 22, IF 'YES':

21.1 What was or is this job? [Be as precise as possible] I*f current job write 'current job'* [ ][ ][ ][ ]

_____

22. Have you ever been involved in an incident at home, work or elsewhere that exposed you to high levels of vapours, gases or fumes? NO [X] YES [ ]

IF NO GO TO Q23; IF YES:

22.1 When did this happen?

a) Less than a year ago a [ ]
b) Between one and five years ago b [ ]
c) More than five years ago c [ ]

22.2 Could you classify this incident as:

a) A fire or an explosion — a ☐
b) A leak or a spill — b ☐
c) (Mixing of) cleaning products — c ☐
d) Something else:_____ — d ☐

22.3 Where did this happen?

a) In your own home — a ☐
b) In your workplace — b ☐
c) Somewhere else indoors — c ☐
d) Outdoors — d ☐

22.4 Did you experience respiratory symptoms within 24 hours following this incident? — NO ☐ YES ☐

23. Have you ever had to change or leave your job because it affected your breathing? — NO ☒ YES ☐

IF 'NO' GO TO QUESTION 24 IF 'YES':

23.1 What was this job? [Be as precise as possible]

_____ ☐☐☐☐

ENVIRONMENT

24. How often do cars pass your house? — TICK ONE BOX ONLY

a) More than 80 per hour — a ☒
b) between 21and 80 per hour — b ☐
c) between 5 and 20 per hour — c ☐
d) less than 5 per hour — d ☐

25. How often do heavy vehicles (e.g. trucks/buses) pass your house? — TICK ONE BOX ONLY

a) More than 20 per hour — a ☒
b) between 4 and 20 per hour — b ☐
c) at least one but less than 4 per hour — c ☐
d) less than one per hour — d ☐

TOBACCO AND ALCOHOL

26. Have you ever smoked for as long as a year? — NO ☐ YES ☒

['YES' means at least 20 packs of cigarettes or 12 oz (360 grams) of tobacco in a lifetime, or at least one cigarette per day or one cigar a week for one year]
IF 'NO' GO TO QUESTION 27, IF 'YES':

26.1 How old were you when you started smoking? — YEARS ☐2☐8

26.2 Do you **now** smoke, as of ***one month ago***? — NO ☒ YES ☐

***IF 'NO' GO TO QUESTION 26.3, IF 'YES'*:**

NUMBER

26.2.1-4 How much do you ***now*** smoke on average

26.2.1 number of cigarettes ***per day*** ☐☐
26.2.2 number of cigarillos ***per day*** ☐☐
26.2.3 number of cigars ***a week*** ☐☐
26.2.4 pipe tobacco in a) ounces / ***week*** ☐☐
b) grams / ***week*** ☐☐☐

NO YES

26.3 Have you stopped or cut down smoking? ☐ ☒

IF 'NO' GO TO QUESTION 26.4, IF 'YES':

YEARS

26.3.1 How old were you when you stopped or cut down smoking? 3 4

26.3.2. 1-4 ***on average*** of the entire time you smoked, before you stopped or cut down, how much did you smoke?

NUMBER

26.3.2.1 number of cigarettes per day	2 0
26.3.2.2 number of cigarillos per day	
26.3.2.3 number of cigars a week	
26.3.2.4 pipe tobacco in a) ounces / week	
b) grams / week	

NO YES

26.4 Do you or did you inhale the smoke? ☒ ☐

NO YES

27. Have you been **regularly** exposed to tobacco smoke in the last ***12months***? ☒ ☐

['Regularly' means on most days or nights]

IF 'NO' GO TO QUESTION 28, IF 'YES':

NUMBER

27.1 Not counting yourself, how many people in your household smoke regularly?

NO YES

27.2 Do people smoke regularly in the room where you work? ☐ ☐

HOURS

27.3 How many hours per day are you exposed to ***other people's*** tobacco smoke?

Please provide more information.

27.8 On average how many hours per day, are you exposed to other peoples tobacco smoke In the following locations

NUMBER

a) At home	a
b) At workplace	b
c) In bars, restaurants, cinemas or similar social settings	c
d) Elsewhere	d

28. How many units of alcohol do you drink daily/weekly?

(one unit = one small bottle of beer (250 ml), a small glass of red or white wine (120 ml) or one shot of spirits (40ml))

TICK ONE BOX ONLY

a) Never	a
b) Less than one a week	b
c) At least one a week but less than one a day	c
d) 1-3 units a day	d
e) 4 units a day	e ☒
f) More than 5 units per day	f

<u>MEDICINES</u>

NO YES

29. Have you used any **inhaled** medicines to help your breathing at any time in the last ***12 months***? ***IF NO' GO TO QUESTION 30, IF 'YES':*** ☒ ☐

What have you used in the last ***12 months***?

INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

NO YES

29.1 **short acting beta-2-agonist inhalers** ☐ ☐

PUFFS

29.1.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

29.2 **long acting beta-2-agonist inhalers** ☐ ☐

PUFFS

29.2.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

29.2.2 Is this a combination with a steroids? ☐ ☐

If YES GO TO QUESTION 29.3.2

NO YES

29.3 **inhaled steroids** **DOSE:_____** ☐ ☐

(***if combined B2 and steroid please insert inhaled steroid dose***)

PUFFS

29.3.1 If used, how many puffs per day have you used **in the last week?** ☐☐

29.3.2 If used, which one? _____ ☐☐☐

NO YES

29.4 **anti-muscarinic inhalers** ☐ ☐

PUFFS

29.4.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

30. Have you used any **pills**, **capsules**, **tablets** or **medicines**, other than inhaled medicines, to help your breathing at any time in the last ***12 months***? ☒ ☐

IF 'NO' GO TO QUESTION 31, IF 'YES':

What have you used in the last ***12 months***?

INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

NO YES

30.1 **oral methylxanthines** ☐ ☐

NO YES

30.2 **oral steroids** ☐ ☐

If used, have you used these in the last 12 months

a. More or less continuously ☐ a

b. More than 2 short courses in the last 12 months ☐ b

c. More than 1 short course in the last 12 months ☐ c

d. A single short course in the last 12 months ☐ d

e ☐ e

NO YES

30.3 **oral anti-leukotrienes** ☐ ☐

NO YES

31. **<u>In the last 5 years</u>** have you ever used inhaled steroids? ☒ ☐

IF NO GO TO QUESTION 32

YEARS

31.1. How old were you when you first started to use inhaled steroids? ☐☐

NO YES

31.2. Have you used inhaled steroids ***every year*** in the last 5 years? ☐ ☐

IF NO GO TO QUESTION 31.3, IF YES

MONTHS

31.2.1. On average how many months each year have you taken them? ☐☐
NOW GO TO Q32

YEARS

31.3 How many of the last 5 years have you taken inhaled steroids? ☐☐

MONTHS

31.4. On average how many months of each of these years have you taken them? ☐☐

USE OF HEALTH SERVICES

	NO	YES	DONT KNOW
32. Have you been vaccinated for allergy in the last 5 years?	☐	☒	☐

IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 33, IF 'YES':

	NO	YES
32.1 Have you been vaccinated for allergy in the last ***12 months***?	☒	☐

	NO	YES
33. In the last 5 years have you visited a hospital casualty department or emergency room because of breathing problems? ***IF NO GO TO Q34, IF YES***	☒	☐

	NO	YES
33.1. Have you visited a hospital casualty department or emergency room because of breathing problems in the ***last 12 months***? ***IF NO GO TO 34, IF YES***	☐	☐

	NO	YES
33.1.1 Was this due to asthma, shortness of breath or wheezing?	☐	☐

TIMES

33.1.2 How many times ***in the last 12 months?*** ☐☐

34 How many nights have you spent in hospital with any of the following conditions in the last 5 years?

	NUMBER OF NIGHTS	
a) Asthma	a	☐0
b) Chest infection	b	☐0
c) COPD	c	☐0
d) Sinusitis	d	☐0
e) Other	e	☐0

	NO	YES
34.1 Have you spent a night in hospital in the ***last 12 months***?	☒	☐

	NO	YES
35. In the last 5 years have you been seen by a doctor because of breathing problems or because of shortness of breath? ***IF NO GO TO Q36, IF YES***	☒	☐

	NO	YES
35.1 Have you been seen by a general practitioner because of breathing problems or shortness of breath in the ***last 12 months? IF NO GO TO Q35.2, IF YES***	☐	☐

NUMBER

35.1.1 How many times? ☐☐

	NO	YES
35.2. Have you seen a specialist (chest physician, allergy specialist, internal medicine specialist, ENT doctor) because of your breathing problems or shortness of breath ***in the last 12 months***?	☐	☐

NUMBER

35.4.1 How many times? | | |

36. Gender

M	F
	☒

37. Date of birth

DAY		MONTH		YEAR	
0	4	1	0	4	9

INTERVIEW TYPE? **TICK ONE BOX ONLY**

a) At centre face to face	a	☒
b) At home face to face	b	
c) By telephone	c	
d) Self completed at home	d	

END FIELDWORKER NUMBER 045

File 5

I AM GOING TO ASK YOU SOME QUESTIONS. AT FIRST THESE WILL BE MOSTLY ABOUT YOUR BREATHING. WHEREVER POSSIBLE, I WOULD LIKE YOU TO ANSWER 'YES' OR 'NO'.

1. Have you had wheezing or whistling in your chest at any time in the last ***12 months***? NO ☐ YES ☑
IF 'NO' GO TO QUESTION 2, IF 'YES':

1.1 Have you been at all breathless when the wheezing noise was present? NO ☑ YES ☐

1.2. Have you had this wheezing or whistling when you did ***not*** have a cold? NO ☐ YES ☑

2. Have you woken up with a feeling of tightness in your chest at any time in the last ***12 months***? NO ☑ YES ☐

3. Have you had an attack of shortness of breath that came on during the day, when you were at rest, at any time in the last ***12 months***? NO ☑ YES ☐

4. Have you had an attack of shortness of breath that came on ***following*** strenuous activity at any time in the last ***12 months***? NO ☑ YES ☐

5. Have you been woken by an attack of shortness of breath at any time in the last ***12 months?*** NO ☑ YES ☐
IF 'NO' GO TO Q6, IF 'YES':

5.1 Have you been woken by an attack of shortness of breath in the last ***3 months***? NO ☐ YES ☐
IF 'NO' GO TO Q6, IF 'YES':

5.1.1 ***On average*** have you been woken by an attack of shortness of breath ***at least once a week*** *in the* ***last 3 months?*** NO ☐ YES ☐
IF 'NO' GO TO Q6, IF 'YES':

5.1.1.1 How many times a week ***on average*** have you been woken by shortness of breath in the ***last 3 months***? TIMES ☐☐

6. Have you been woken by an attack of coughing at any time in the ***last 12 months***? NO ☑ YES ☐

7. Do you ***usually*** cough first thing in the morning in the winter? NO ☑ YES ☐
[IF DOUBTFUL, USE QUESTION 8.1 TO CONFIRM]

8. Do you ***usually*** cough during the day, or at night, in the winter? NO ☑ YES ☐
IF 'NO' GO TO QUESTION 9, IF 'YES':

8.1 Do you cough like this on most days for as much as three months each year? NO ☐ YES ☐

9. Do you ***usually*** bring up any phlegm from your chest first thing in the morning in the winter? **[IF DOUBTFUL, USE QUESTION 10.1 TO CONFIRM]** NO ☑ YES ☐

10.Do you ***usually*** bring up any phlegm from your chest during the day, or at night, in the winter? NO ☐ YES ☐
'NO' GO TO QUESTION 11, IF 'YES':

10.1 Do you bring up phlegm like this on most days for as much as three months each year? NO ☐ YES ☐

NO YES

11. Are you disabled from walking by a condition ***other than*** heart or lung disease? ✓

IF 'YES' STATE TYPE OF CONDITION IN THE BOX BELOW AND GO TO QUESTION 12, IF 'NO' GO TO Q11.1:

a) bone and joint problems	a	
b) neurological including stroke	b	
c) vascular including amputations	c	
d) accidents	d	
e) other	e	
NOW GO TO Q12		

NO YES

11.1 Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill? ✓ ***IF 'NO' GO TO QUESTION 12, IF 'YES':***

NO YES

11.1.1 Do you get short of breath walking with other people of your own age on level ground? ***IF 'NO' GO TO QUESTION 12, IF 'YES':***

NO YES

11.1.1.1 Do you have to stop for breath when walking at your own pace on level ground?

NO YES

12. Have you ***ever*** had asthma? ✓

IF 'NO' GO TO QUESTION 13, IF 'YES':

NO YES

12.1 Was this confirmed by a doctor? ✓

YEARS

12.2 How old were you when you had your first attack of asthma? 2 2

YEARS

12.3 How old were you when you had your most recent attack of asthma? 3 2

NO YES

12.4 Have you had an attack of asthma in the last ***12 months***? ✓

IF 'NO' GO TO 12.7, IF' YES':

ATTACKS

12.5 How many attacks of asthma have you had in the last ***12 months***? 0 0

IF 'NONE', GO TO 12.7, IF 'YES':

ATTACKS

12.6 How many attacks of asthma have you had in the last ***3 months***? 0 0

12.7 How many times have you woken up because of your asthma in the last ***3 months?*** TICK ONE BOX ONLY

a) every night or almost every night	a	
b) more than once a week, but not most nights	b	
c) at least twice a month, but not more than once a week	c	
d) less than twice a month	d	
e) not at all	e	✓

12.8. How often have you had trouble with your breathing because of your asthma in the last ***3 months?*** TICK ONE BOX ONLY

a) continuously	a	
b) about once a day	b	
c) at least once a week, but less than once a day	c	
d) less than once a week	d	
e) not at all	e	✓

NO YES

12.9 Are you currently taking any medicines including inhalers, aerosols or tablets for ✓

asthma?

	NO	YES
13. Do you have any nasal allergies, including hay fever?		✓

IF 'NO' GO TO Q14, IF' YES':

	YEARS
13.1 How old were you when you first had hay fever or nasal allergy?	2 4

	NO	YES
14. Have you ***ever*** had a problem with sneezing, or a runny or a blocked nose when you did not have a cold or the flu?		✓

IF 'NO' GO TO Q17, IF 'YES':

	NO	YES
14.1. Have you had a problem with sneezing or a runny or a blocked nose when you did not have a cold or the flu ***in the last 12 months***?		✓

IF 'NO' GO TO Q15, IF' YES':

	NO	YES
14.1.1. Has this nose problem been accompanied by itchy or watery eyes?		✓

14.1.2. In which months of the year did this nose problem occur?	NO	YES
January	✓	
February	✓	
March	✓	
April	✓	
May	✓	
June	✓	
July	✓	
August	✓	
September	✓	
October	✓	
November	✓	
December	✓	

14.1.3. Is this set off by:	NO	YES
Grass pollen		✓
Tree pollen	✓	
Weed pollen	✓	
Moulds	✓	
Animals	✓	
Perfumes, smells or smoke	✓	
Changes in the temperature		✓
Changes in position (such as lying down)	✓	

	NO	YES
15. ***In the last 5 years*** have you used any medication to treat problems in your nose, or hayfever?	✓	

	NO	YES
16. In the last 5 years have you ever used **nasal** steroids?	✓	

IF 'NO' GO TO QUESTION 17 IF 'YES':

	YEARS
16.1. How old were you when you first started to use **nasal** steroids?	

	NO	YES
16.2. Have you used **nasal** steroids ***every year*** in the last 5 years?		

IF 'NO' GO TO QUESTION 16.3, IF 'YES':

	MONTHS
16.2.1. On average how many months each year have you taken them?	

NOW GO TO Q17

16.3 How many of the last 5 years have you taken **nasal** steroids? — YEARS ☐☐

16.4. On average how many months of each of these years have you taken them? — MONTHS ☐☐

17. In the last 5 years have you ever used **antihistamine tablets, medicines, nasal sprays or eye drops?** ***IF NO, GO TO QUESTION 18*** — NO ✓ YES ☐

17.1. How old were you when you first started to use these **antihistamines**? — YEARS ☐☐

17.2. Have you used these **antihistamines** ***every year*** in the last 5 years? — NO ☐ YES ☐
IF 'NO' GO TO QUESTION 17.3, IF'YES':

17.2.1. On average how many months each year have you taken them? — MONTHS ☐☐
NOW GO TO Q18

17.3 How many of the last 5 years have you taken **antihistamines**? — YEARS ☐☐

17.4. On average how many months of each of these years have you taken them? — MONTHS ☐☐

18**.** Has your nose been blocked **for more than 12 weeks during the last 12 months?** — NO ✓ YES ☐
IF 'NO' GO TO Q19, IF 'YES':

18.1 How old were you when you first had this symptom? — YEARS ☐☐

18.2 How often have you had this symptom in the last month? — TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

19. Have you had pain or pressure around the forehead, nose or eyes **for more than 12 weeks during the last 12 months?** — NO ✓ YES ☐
IF 'NO' GO TO Q20, IF 'YES':

19.1 How old were you when you first had this symptom? — YEARS ☐☐

19.2 How often have you had this symptom in the last month? — TICK ONE BOX ONLY

a) Not at all	a ☐
b) Less than once a week	b ☐
c) At least once a week, but less than once a day	c ☐
d) About once a day	d ☐
e) Continuously	e ☐

20**.** Have you had discoloured nasal discharge (snot) or discoloured mucus in the throat **for more than 12 weeks during the last 12 months?** — NO ✓ YES ☐
IF 'NO' GO TO QUESTION 21, IF 'YES':

20.1 How old were you when you first had this symptom? — YEARS ☐☐

20.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all a ☐
b) Less than once a week b ☐
c) At least once a week, but less than once a day c ☐
d) About once a day d ☐
e) Continuously e ☐

NO YES

21**.** Has your sense of smell been reduced or absent **<u>for more than 12 weeks during the last 12 months</u>?** ☑ ☐

IF 'NO' GO TO QUESTION 22, IF 'YES':

YEARS

21.1 How old were you when you first had this symptom? ☐☐

21.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all a ☐
b) Less than once a week b ☐
c) At least once a week, but less than once a day c ☐
d) About once a day d ☐
e) Continuously e ☐

NO YES

22. Have you had mucus in your throat **for more than 12 weeks during the last 12 months**? ☑ ☐

IF 'NO' GO TO QUESTION 23, IF 'YES':

YEARS

22.1 How old were you when you first had this symptom? ☐☐

22.2 How often have you had this symptom in the last month? TICK ONE BOX ONLY

a) Not at all a ☐
b) Less than once a week b ☐
c) At least once a week, but less than once a day c ☐
d) About once a day d ☐
e) Continuously e ☐

NO YES

23**.** Has a doctor ***ever*** told you that you have **<u>chronic</u>** sinusitis or nasal polyps? ☑ ☐

IF 'NO' GO TO QUESTION 24, IF 'YES':

YEARS

23.1 How old were you when you first had sinusitis OR nasal polyps? ☐☐

YEARS

23.2 How old were you when you were first diagnosed as having chronic sinusitis OR nasal polyps? ☐☐

23.3. How did your sinus problems start? TICK ONE BOX ONLY

a) Headache or pressure over the sinuses a ☐
b) Loss of smell b ☐
c) A common cold c ☐
d) Frequent episodes of acute sinusitis d ☐
e) None of the above e ☐

23.4 If you also get asthma, how does this relate to your sinus problems? TICK ONE BOX ONLY

a) I don't get asthma a ☐
b) Sinusitis usually comes before the asthma worsens b ☐
c) Asthma usually comes before the sinusitis worsens c ☐

d) Both usually start with a common cold d ☐
e) None of the above e ☐

NO YES N/A

23.5 If you drink alcohol does this worsen your sinus problems? ☐ ☐ ☐

23.5.1 - 4 ***IF 'NO' or N/A, skip to 23.6 ; IF 'YES', which symptoms does alcohol affect?***

NO YES

23.5.1 Blocked Nose ☐ ☐
23.5.2 Runny Nose ☐ ☐
23.5.3 Post nasal drip (mucus in the throat) ☐ ☐
23.5.4 Sneezing ☐ ☐

NO YES

23.6 Have you ***ever*** had surgery for nasal/sinus problems? ☐ ☐

NO YES

23.7. In the last 5 years have you ever used **antibiotics for nasal/sinus problems**? ☐ ☐
IF 'NO' GO TO QUESTION 24

YEARS

23.8. How old were you when you first started to use **antibiotics for nasal/sinus problems**? ☐☐

NO YES

23.9. Have you used **antibiotics for nasal/sinus problems *every year*** in the last 5 years? ☐ ☐
IF 'NO' GO TO QUESTION 23.10, IF 'YES':

MONTHS

23.9.1. On average how many months each year have you taken them? ☐☐
NOW GO TO Q24

YEARS

23.10 How many of the last 5 years have you taken **antibiotics for nasal/sinus problems**? ☐☐

MONTHS

23.11. On average how many months of each of these years have you taken them? ☐☐

NO YES

24. Have you ***ever*** had eczema or any kind of skin allergy? ✓ ☐
IF 'NO' GO TO Q25, IF 'YES':

NO YES

24.1. Was this problem ***ever*** associated with your work? ☐ ☐
IF 'NO' GO TO QUESTION 25, IF 'YES':

24.2. What job were you doing that made it worse? ☐☐☐☐
_____

NO YES

24.3. Do you know what caused the problem at work? ☐ ☐
IF 'YES' What was this problem?_____

NO YES

25. Have you ***ever*** had an itchy rash that was coming and going for at ***least 6 months***? ✓ ☐
IF 'NO' GO TO QUESTION 26, IF 'YES':

NO YES

25.1. Have you had this itchy rash ***in the last 12 months?*** ☐ ☐
IF 'NO' GO TO QUESTION 26, IF 'YES':

NO YES

25.1.1. Has this itchy rash ***at any time*** affected any of the following places: the folds of the elbows, behind the knees, in front of the ankles under the buttocks or around the neck, ears or eyes? ☐ ☐

NO YES

25.1.2. Does this itchy rash affect your hands? ☐ ☐

NO YES

26. Have you ***ever*** had any difficulty with your breathing after taking medicines? ☑ ☐

IF 'NO' GO TO QUESTION 27 IF 'YES':

26.1 Which medicines? _____ 26.1.1 ☐
26.1.2 ☐

NO YES

27. Have you ***ever*** had a runny or a stuffy nose or sneezing after taking medicines? ☑ ☐

IF 'NO' GO TO QUESTION 28, IF 'YES':

27.1 Which medicines? _____ 27.1.1 ☐
27.1.2 ☐

NO YES

28. Have you ***ever*** had uticaria, nettle rash or hives after taking medicines? ☑ ☐

IF 'NO' GO TO QUESTION 29, IF 'YES':

28.1 Which medicines? _____ 28.1.1 ☐
28.1.2 ☐

NO YES

29. Have you ***ever*** had an illness or trouble caused by eating a ***particular*** food or foods? ☑ ☐

IF 'YES' GO TO QUESTION 29.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

NO YES

29.1 Have you nearly always had the same illness or trouble after eating this type of food? ☐ ☐

IF 'YES' GO TO QUESTION 29.1.1 IF 'NO', YOU HAVE FINISHED THIS SECTION. NOW PLEASE GO TO THE FURTHER QUESTIONS SECTION. THANK YOU

29.1.1 What type of food was this? [List up to 3]

_____29.1.1.1 ☐☐
_____29.1.1.2 ☐☐
_____29.1.1.3 ☐☐

29.1.2 Did this illness or trouble include:

	NO	YES
29.1.2.1. Itching, tingling or swelling in the mouth, lips or throat?	☐	☐
29.1.2.2. A rash, nettle sting like rash or itchy skin?	☐	☐
29.1.2.3. Diarrhoea or vomiting (other than food poisoning)?	☐	☐
29.1.2.4. Runny or stuffy nose?	☐	☐
29.1.2.5. Red, sore or running eyes?	☐	☐
29.1.2.6. Difficulty swallowing?	☐	☐
29.1.2.7. Breathlessness?	☐	☐
29.1.2.8. Stiffness in your joints?	☐	☐
29.1.2.9. Fainting or dizziness?	☐	☐
29.1.2.10. Headaches?	☐	☐

SOME FURTHER QUESTIONS

1. How old was your mother when you were born? — YEARS: 2 6

2. Were you hospitalised before the age of two years for lung disease? — NO ✓ / YES

Your parents' smoking

3. Did your father ***ever*** smoke regularly during your childhood? — NO / YES ✓ / DON'T KNOW

4. Did your mother ***ever*** smoke regularly during your childhood, or before you were born? — NO ✓ / YES / DON'T KNOW

IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 5, IF 'YES':

4.1 When your mother was pregnant, in particular with you, did she: — TICK ONE BOX ONLY

a) Stop smoking before pregnancy? a
b) Cut down or stop during pregnancy? b
c) Smoke as usual during pregnancy? c
d) Don't know d

5. What country were you born in? _____England_____

6. How many brothers do or did you have? — NUMBER: 0 1

IF 'NONE' GO TO QUESTION 7, IF 'ONE OR MORE':

NUMBER

6.1 How many ***older*** brothers? 0 0
6.2 How many ***younger*** brothers? 0 1
6.3 How many of your brothers ever had asthma? 0 0

6.4 How many of your ***other*** brothers ever had eczema, skin or nasal allergy or hay fever? — NUMBER: 0 0

7. How many sisters do or did you have? — NUMBER: 0 1

IF 'NONE' GO TO QUESTION 8, IF 'ONE OR MORE':

NUMBER

7.1 How many ***older*** sisters? 0 0
7.2 How many ***younger*** sisters? 0 1
7.3 How many of your sisters ever had asthma? 0 0
7.4 How many of your ***other*** sisters ever had eczema, skin or nasal allergy or hay fever? 0 0

8. Did your mother ***ever*** have asthma? — NO ✓ / YES / DON'T KNOW

9. Did your mother ***ever*** have eczema, skin or nasal allergy or hay fever? — NO ✓ / YES / DON'T KNOW

10. Did your father ***ever*** have asthma? — NO ✓ / YES / DON'T KNOW

	NO	YES	DON'T KNOW
11. Did your father ***ever*** have eczema, skin or nasal allergy or hay fever?		✓	
12. Did you regularly share your bedroom with any ***older*** children before the age of five years?	✓		
13. Did you go to a school, play-school or nursery with ***older*** children before the age of five years?			✓
14. Did you have a serious respiratory infection before the age of five years?	✓		

	NO	YES	DONT KNOW
15. Was there a dog in your home?			
15.1 During your first year of life	✓		
15.2 When you were aged 1 to 4 years	✓		
15.3 When you were aged 5-15 years	✓		
16. Was there a cat in your home?			
16.1. During your first year of life	✓		
16.2 When you were aged 1 to 4 years	✓		
16.3 When you were aged 5-15 years	✓		

17. What term best describes the place you lived most of the time when you were under the age of five years?

	TICK ONE BOX ONLY	
a) Farm	a	
b) Village in a rural area	b	
c) Small town	c	
d) Suburb of a city	d	✓
e) Inner city	e	

WORK AND EDUCATION

	NO	YES
18. Are you a full time student?	✓	

IF 'YES' GO TO QUESTION 21, IF 'NO':

	YEARS
18.1 At what age did you complete full time education?	3 0

I would now like to ask you some questions on the type of jobs that you have done.

18.2. Are you currently:	TICK ONE BOX ONLY	
Employed (including military service)	1	✓
Self employed	2	
Unemployed, looking for work	3	
Not working because of poor health	4	
Full-time house-person	5	
Full time student	6	
Retired	7	
Other	8	

	NO	YES

18.3 Have you ***ever*** had a job for more than three consecutive months? ☐ ✓

IF 'NO' GO TO Q22, IF 'YES':

YEARS

18.4 How old were you when you started your first job? 2 6

18.5. What was this first job? (*be as precise as possible*)

_____Medical Doctor_____

NO YES

18.6. Would you say that allergies or breathing problems influenced your **initial** job choice? ✓ ☐

NO YES

18.7. Would you say that allergies or breathing problems are likely to influence your **future** job choices? ✓ ☐

NO YES

18.8. Are you currently still working in your first job (as in question 18.4)? ✓ ☐

IF 'YE'S, GO TO Q18.11, IF 'NO':

18.9 What is your current or most recent job? [Be as precise as possible, if not working, please complete as Not Working]

_____Senior Lecturer _____

YEARS

18.10 How old were you when you started working in this job? 4 1

18.11 In this job were you: TICK ONE BOX ONLY

a) A manager working for an employer? a ☐
b) A foreman or supervisor working for an employer? b ☐
c) Working for an employer, but neither a manager, supervisor or foreman? c ✓
d) Self-employed? d ☐

NO YES

19. Does or did being at work ever make your chest tight or wheezy? ✓ ☐

NO YES

19.1 Is or was your breathing better at weekends or holidays? ☐ ☐

DAYS

20. How many days of work have you lost because of asthma, shortness of breath or wheezing in the last **12 months?** **0 0 0**

NO YES

21. Have you ever worked in a job which exposed you to vapours, gas, dust or fumes? ✓ ☐

IF 'NO' GO TO QUESTION 22, IF 'YES':

21.1 What was or is this job? [Be as precise as possible] I*f current job write 'current job'*

_____

NO YES

22. Have you ever been involved in an incident at home, work or elsewhere that exposed you to high levels of vapours, gases or fumes? ✓ ☐

IF NO GO TO Q23; IF YES:

22.1 When did this happen?

a) Less than a year ago a ☐
b) Between one and five years ago b ☐
c) More than five years ago c ☐

22.2 Could you classify this incident as:

a) A fire or an explosion — a ☐
b) A leak or a spill — b ☐
c) (Mixing of) cleaning products — c ☐
d) Something else:_____ — d ☐

22.3 Where did this happen?
a) In your own home — a ☐
b) In your workplace — b ☐
c) Somewhere else indoors — c ☐
d) Outdoors — d ☐

22.4 Did you experience respiratory symptoms within 24 hours following this incident? — NO ☐ YES ☐

23. Have you ever had to change or leave your job because it affected your breathing? — NO ☑ YES ☐
IF 'NO' GO TO QUESTION 24 IF 'YES':
23.1 What was this job? [Be as precise as possible]
_____ ☐☐☐☐

ENVIRONMENT

24. How often do cars pass your house? — TICK ONE BOX ONLY
a) More than 80 per hour — a ☑
b) between 21and 80 per hour — b ☐
c) between 5 and 20 per hour — c ☐
d) less than 5 per hour — d ☐

25. How often do heavy vehicles (e.g. trucks/buses) pass your house? — TICK ONE BOX ONLY
a) More than 20 per hour — a ☐
b) between 4 and 20 per hour — b ☑
c) at least one but less than 4 per hour — c ☐
d) less than one per hour — d ☐

TOBACCO AND ALCOHOL

26. Have you ever smoked for as long as a year? — NO ☑ YES ☐
['YES' means at least 20 packs of cigarettes or 12 oz (360 grams) of tobacco in a lifetime, or at least one cigarette per day or one cigar a week for one year]
IF 'NO' GO TO QUESTION 27, IF 'YES':

26.1 How old were you when you started smoking? — YEARS ☐☐

26.2 Do you **now** smoke, as of ***one month ago***? — NO ☐ YES ☐
***IF 'NO' GO TO QUESTION 26.3, IF 'YES'*:**

NUMBER

26.2.1-4 How much do you ***now*** smoke on average
26.2.1 number of cigarettes ***per day*** ☐☐
26.2.2 number of cigarillos ***per day*** ☐☐
26.2.3 number of cigars ***a week*** ☐☐
26.2.4 pipe tobacco in a) ounces / ***week*** ☐☐
b) grams / ***week*** ☐☐☐

26.3 Have you stopped or cut down smoking? — NO ☐ YES ☐

IF 'NO' GO TO QUESTION 26.4, IF 'YES':

YEARS

26.3.1 How old were you when you stopped or cut down smoking? ☐☐

26.3.2. 1-4 ***on average*** of the entire time you smoked, before you stopped or cut down, how much did you smoke?

NUMBER

26.3.2.1 number of cigarettes per day	☐☐
26.3.2.2 number of cigarillos per day	☐☐
26.3.2.3 number of cigars a week	☐☐
26.3.2.4 pipe tobacco in a) ounces / week	☐☐
b) grams / week	☐☐☐

NO YES

26.4 Do you or did you inhale the smoke? ☐ ☐

NO YES

27. Have you been **regularly** exposed to tobacco smoke in the last ***12months***? ✓ ☐
['Regularly' means on most days or nights]

IF 'NO' GO TO QUESTION 28, IF 'YES':

NUMBER

27.1 Not counting yourself, how many people in your household smoke regularly? ☐☐

NO YES

27.2 Do people smoke regularly in the room where you work? ☐ ☐

HOURS

27.3 How many hours per day are you exposed to ***other people's*** tobacco smoke? ☐☐

Please provide more information.

27.4 On average how many hours per day, are you exposed to other peoples tobacco smoke In the following locations

NUMBER

a) At home	a	☐☐
b) At workplace	b	☐☐
c) In bars, restaurants, cinemas or similar social settings	c	☐☐
d) Elsewhere	d	☐☐

28. How many units of alcohol do you drink daily/weekly?
(one unit = one small bottle of beer (250 ml), a small glass of red or white wine (120 ml) or one shot of spirits (40ml))

TICK ONE BOX ONLY

a) Never	a	☐
b) Less than one a week	b	☐
c) At least one a week but less than one a day	c	✓
d) 1-3 units a day	d	☐
e) 4 units a day	e	☐
f) More than 5 units per day	f	☐

MEDICINES

NO YES

29. Have you used any **inhaled** medicines to help your breathing at any time in the last ***12 months***? ☒ ☐
IF NO' GO TO QUESTION 30, IF 'YES':

What have you used in the last ***12 months***?
INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

NO YES

29.1 **short acting beta-2-agonist inhalers** ☐ ☐

PUFFS

29.1.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

29.2 **long acting beta-2-agonist inhalers** ☐ ☐

PUFFS

29.2.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

29.2.2 Is this a combination with a steroids? ☐ ☐

If YES GO TO QUESTION 29.3.2

NO YES

29.3 **inhaled steroids** **DOSE:_____** ☐ ☐

(***if combined B2 and steroid please insert inhaled steroid dose***)

PUFFS

29.3.1 If used, how many puffs per day have you used **in the last week?** ☐☐

29.3.2 If used, which one? _____ ☐☐☐

NO YES

29.4 **anti-muscarinic inhalers** ☐ ☐

PUFFS

29.4.1 If used, how many puffs per day have you used **in the last week?** ☐☐

NO YES

30. Have you used any **pills**, **capsules**, **tablets** or **medicines**, other than inhaled medicines, to help your breathing at any time in the last ***12 months***? ✓ ☐

IF 'NO' GO TO QUESTION 31, IF 'YES':

What have you used in the last ***12 months***?

INTERVIEWER TO CODE UNDER THE FOLLOWING CATEGORIES

NO YES

30.1 **oral methylxanthines** ☐ ☐

NO YES

30.2 **oral steroids** ☐ ☐

If used, have you used these in the last 12 months a

a. More or less continuously ☐ b

b. More than 2 short courses in the last 12 months ☐ c

c. More than 1 short course in the last 12 months ☐ d

d. A single short course in the last 12 months ☐ e

NO YES

30.3 **oral anti-leukotrienes** ☐ ☐

NO YES

31. **<u>In the last 5 years</u>** have you ever used inhaled steroids? ✓ ☐

IF NO GO TO QUESTION 32

YEARS

31.1. How old were you when you first started to use inhaled steroids? ☐☐

NO YES

31.2. Have you used inhaled steroids ***every year*** in the last 5 years? ☐ ☐

IF NO GO TO QUESTION 31.3, IF YES

MONTHS

31.2.1. On average how many months each year have you taken them? ☐☐
NOW GO TO Q32

YEARS

31.3 How many of the last 5 years have you taken inhaled steroids? ☐☐

MONTHS

31.4. On average how many months of each of these years have you taken them? ☐☐

USE OF HEALTH SERVICES

	NO	YES	DONT KNOW
32. Have you been vaccinated for allergy in the last 5 years?	✓		

IF 'NO' OR 'DON'T KNOW' GO TO QUESTION 33, IF 'YES':

	NO	YES
32.1 Have you been vaccinated for allergy in the last ***12 months***?		

	NO	YES
33. In the last 5 years have you visited a hospital casualty department or emergency room because of breathing problems? ***IF NO GO TO Q34, IF YES***	✓	

	NO	YES
33.1. Have you visited a hospital casualty department or emergency room because of breathing problems in the ***last 12 months***? ***IF NO GO TO 34, IF YES***		

	NO	YES
33.1.1 Was this due to asthma, shortness of breath or wheezing?		

TIMES

33.1.2 How many times ***in the last 12 months*****?** ☐☐

34 How many nights have you spent in hospital with any of the following conditions in the last 5 years?

	NUMBER OF NIGHTS	
a) Asthma	a	0 0
b) Chest infection	b	0 0
c) COPD	c	0 0
d) Sinusitis	d	0 0
e) Other	e	0 0

	NO	YES
34.1 Have you spent a night in hospital in the ***last 12 months***?		

	NO	YES
35. In the last 5 years have you been seen by a doctor because of breathing problems or because of shortness of breath? ***IF NO GO TO Q36, IF YES***	✓	

	NO	YES
35.1 Have you been seen by a general practitioner because of breathing problems or shortness of breath in the ***last 12 months? IF NO GO TO Q35.2, IF YES***	✓	

NUMBER

35.1.1 How many times? ☐☐

	NO	YES
35.2. Have you seen a specialist (chest physician, allergy specialist, internal medicine specialist, ENT doctor) because of your breathing problems or shortness of breath ***in the last 12 months***?	✓	

NUMBER

35.4.1 How many times? ☐☐

	M	F
36. Gender	✓	

	DAY	MONTH	YEAR
37. Date of birth	1 2	1 2	5 8

INTERVIEW TYPE?	**TICK ONE BOX ONLY**	
a) At centre face to face	a	✓
b) At home face to face	b	
c) By telephone	c	
d) Self completed at home	d	
END FIELDWORKER NUMBER		

Appendix 13

MDI CHECKLIST

❑ Shook the inhaler 10-15 seconds prior to use.

❑ Exhaled fully prior to inhalation.

❑ Tipped chin up prior to inhalation.

❑ Inhaler was held level and discharged with the index or middle finger on top of the medication canister and the thumb supporting the inhaler's bottom.

❑ Lips closed - spacer between teeth during discharge.

❑ Inhaled slowly and deeply after inhaler discharged.

❑ Breath held for at least 10 seconds after inhalation.

❑ Wait two or more minutes before giving second puff

_____

_____

Certifier Date (DDMMYY)

Appendix 14 Allergy Skin Test Training Sheet

Participant Initials

Carry out two histamine skin prick tests on each participant. Record diameters to the nearest mm.

Participant name / number: _____ Date:

TEST 1 (1st diam, 2nd diam, Mean) TEST 2 (1st diam, 2nd diam, Mean)

Participant name / number :_____ Date:

TEST 1 (1st diam, 2nd diam, Mean) TEST 2 (1st diam, 2nd diam, Mean)

Participant name / number: _____ Date:

TEST 1 (1st diam, 2nd diam, Mean) TEST 2 (1st diam, 2nd diam, Mean)

Participant name / number: _____ Date:

TEST 1 (1st diam, 2nd diam, Mean) TEST 2 (1st diam, 2nd diam, Mean)

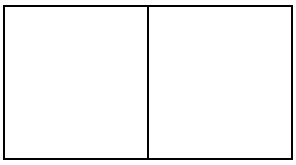
Participant name / number: _____ Date:

TEST 1 (1st diam, 2nd diam, Mean) TEST 2 (1st diam, 2nd diam, Mean)

Participant name / number: _____ Date:

TEST 1 (1st diam, 2nd diam, Mean) TEST 2 (st diam, 2nd diam, Mean)

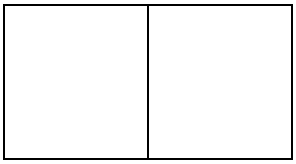
Participant name / number: _____ Date:



TEST 1 ☐ 1st diam ☐ 2nd diam ☐ Mean

TEST 2 ☐ 1st diam ☐ 2nd diam ☐ Mean

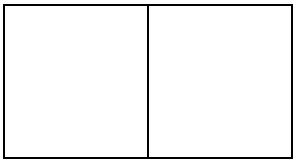
Participant name / number: _____ Date:



TEST 1 ☐ 1st diam ☐ 2nd diam ☐ Mean

TEST 2 ☐ 1st diam ☐ 2nd diam ☐ Mean

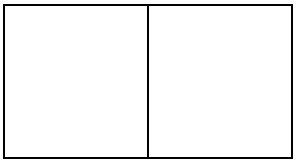
Participant name / number: _____ Date:



TEST 1 ☐ 1st diam ☐ 2nd diam ☐ Mean

TEST 2 ☐ 1st diam ☐ 2nd diam ☐ Mean

Participant name / number: _____ Date:



TEST 1 ☐ 1st diam ☐ 2nd diam ☐ Mean

TEST 2 ☐ 1st diam ☐ 2nd diam ☐ Mean

Calculation of CV

If 2 Tests Carried Out On Each Participant:

	Mean diam TEST 1 (A)	Mean diam TEST 2 (B)	Log_e (A)	Log_e (B)	d	d^2	$d^2/2$
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
				$\sum d^2/2$			

$$\frac{\sum d^2/2}{n}$$

Coefficient of variation $CV = \sqrt{\frac{\Sigma(d^2/2)}{n}} \times 100 =$

where diam= diameter
$\log_e$ = log to base e
d = $\log_e$ (mean diam 1) - $\log_e$ (mean diam 2)
n = number of participants

Reference: Chinn S. The assessment of methods of measurement. Statistics in Medicine 1990; 9:351-62

Appendix 15 Sample Log

Study: **GA²LEN Survey Follow Up Study**

Centrifugation Speed: 3000 rpm Centrifugation Time: **15 minutes**

Freezer Temperature: **-20 °c** Samples: **Serum, whole blood** (not to be spun)

Bar code Label	Date sample taken	Date sample spun	No. of (2ml) aliquots stored	No. of 6ml blood tubes stored	Storage Box Number	Initials
			Serum	Whole blood		

Freezer temp	Date	Initials

Appendix 16

EasyOne configuration settings

Test settings:

Parameter	Ga^{2}len Setting
Predicted:	ERS/ECCS
Add.Ped:	(blank)
Value Sel:	Best Value
Interpretation:	(blank)
Lung Age:	OFF
Automated QC:	ON
FVC Selection:	FVC
PEF Unit:	L/s
AfricanEthnCorr:	88%
AsianEthnCorr:	100%
HispanicEthnCorr:	100%
OtherEthnCorr:	100%
Storage:	3 Best IMPORTANT!!

General Settings:

Parameter	Ga^{2}len Setting
Time Form:	24 hour
Date Form:	DD/MM/YY
Date:	Enter date
Time:	Enter local time
Alpha-ID:	No
Tech.ID:	Yes
SyringeVol:	3.0L
Height Unit:	m/cm
Weight Unit:	Kg
Age/Birth:	Age
LCDContrast:	40 (or as needed)
Language:	English
Altitude:	0 (or nearest 500meters)
Mode	DIAGNOSTIC
Temperature	°C
Humidity	Enter average

Report Settings:

Parameter	Ga^{2}lenSetting
Printer:	Via PC
Data:	3 Best Data
Curve:	3 Best
Graph:	Small FV&VT
Headers (1-4)	Enter the headers you want

Appendix 17 Smell Test

Sniffin' Sticks 1

SMELL TEST
Identification Screening 12

- ORANGE
- STRAWBERRY
- BLACKBERRY
- PINEAPPLE

Sniffin' Sticks 2

SMELL TEST
Identification Screening 12

- SMOKE
- LEATHER
- GLUE
- GRASS

Sniffin' Sticks 3

SMELL TEST
Identification Screening 12

- HONEY
- CHOCOLATE
- VANILLA
- CINNAMON

Sniffin' Sticks 4

SMELL TEST
Identification Screening 12

- CHIVE
- FIR
- PEPPERMINT
- ONION

Sniffin' Sticks 5

SMELL TEST
Identification Screening 12

- COCONUT
- WALNUT
- BANANA
- CHERRY

Sniffin' Sticks 6

SMELL TEST
Identification Screening 12

- PEACH
- LEMON
- APPLE
- GRAPEFRUIT

Sniffin' Sticks 7

SMELL TEST
Identification Screening 12

- LIQUORICE
- SPEARMINT
- GUM
- COOKIES

Sniffin' Sticks 8

SMELL TEST
Identification Screening 12

- CIGARETTE
- WINE
- COFFEE
- SMOKE

Sniffin' Sticks 9 SMELL TEST

Identification Screening 12

- CLOVES
- CINNAMON
- PEPPER
- MUSTARD

Sniffin' Sticks 10 SMELL TEST

Identification Screening 12

- PEAR
- PEACH
- PLUM
- PINEAPPLE

Sniffin' Sticks 11 SMELL TEST

Identification Screening 12

- CAMOMILE
- ROSE
- RASPBERRY
- CHERRY

Sniffin' Sticks 12 SMELL TEST

Identification Screening 12

- BREAD
- CHEESE
- FISH
- HAM

Appendix 18

ISCO 88 Codes

Please purchase ILO International Standard Classification of Occupations: ISCO-88, Geneva, International labour Office, 1990

ISBN 92-2-106438-7

This edition is available in English, French and Spanish

Appendix 19

Main Questionnaire instructions

Survey Follow Up
Main Questionnaire

Introduction

The use of a questionnaire to collect information makes it possible to obtain answers to important questions in a standardised way. The reliability of the questionnaire depends on the behaviour of the interviewer, and therefore it is important that the questions are read exactly as they are printed and that no non-verbal clues are given.

Basic rules

1. Interviews should take place where there is minimal disturbance, where both interviewer and subject can be comfortable, and where eye contact and hence the attention of the subject can be maintained.
2. The interview is started when the interviewer has the subject's full attention, with the introductory sentence used in the questionnaire.
3. Occasionally, the interview may be complicated by one of the following difficulties:
a) The subject will not understand the question.
b) The subject or interviewer will find an ambiguity in the question.
c) The subject's answer may be inappropriate to the question.
4. It is very important that all interviewers in all the centres follow the same procedure for solving problems, so that it is possible to compare the answers given in one centre with the answers given in another.
5. The following general rules should be obeyed when there is a problem:
a) The question is repeated exactly as it is written, emphasising the wording where there is an ambiguity or misunderstanding.
b) The subject is reminded that he/she should try to answer 'yes' or 'no' to each of the questions.
c) If an answer of 'yes' or 'no' is required and the subject does not understand the question even when repeated, the answer is coded as 'NO'.
d) Where an answer is required to a quantitative or semi-quantitative question, the subject's 'best guess' may be accepted.
e) If an explanation may be given to the subject, instructions for these are provided. Words in the question that should be stressed are underlined. Notes in square brackets are for guidance and should not be read out.

If, during the interview, a subject requests further information or clarification of a question that is not possible according to the questionnaire rules, the interviewer should explain to the subject that these points can be discussed at the end of the questionnaire.

The word 'asthma' is considered to be emotive and it is generally replaced by the words 'respiratory health' or 'breathing problems'. If the word 'asthma' does not appear in the question it should not be used in any further clarification or discussion with the subject.

Training

Before starting the survey, the questionnaire and instructions should be studied and any difficulties discussed. Trainee interviewers must become familiar with the flow of questions. Interviewers should test the questionnaire on 10 or more subjects (such as hospital patients), who have at least some chest symptoms, as there is usually no difficulty with subjects who answer 'no'. These interviews should be witnessed by an experienced person who can identify mistakes or doubtful points that need correcting or clarification.

Recording the replies to the questions

Most of the questions are of the 'YES' or 'NO' type and where applicable 'DON'T KNOW'. If there is not provision for a 'Don't know' answer and the subject is uncertain of the answer it is recorded as 'NO'. If the answer to the question is a number, this should be recorded directly in the boxes provided. Where the answer is a date, this should be written in the boxes, one number per box. When the answer is a word it is written out in full. The interviewer should follow instructions given in the questionnaire regarding which questions to ask according to the subject's responses. In cases when further questions are irrelevant (and this can follow a 'YES' or a 'NO' answer) a 'skip' ('GO TO') will direct interviewers to the next question. Occasionally, there are 'skips' within sub-divisions of questions. For questions where there is a choice of answers there are two formats. If there is only one possible or likely answer the format is 'TICK ONE BOX ONLY'. If the subject cannot decide between two options, then the choice which applies most of the time and most recently should be recorded. The second format is a 'YES / NO' box to each of a number of possibilities or choices in cases where they could all apply. Some of these questions have as a final option 'OTHER'. If the subject chooses this option and, therefore, gives an unusual or unexpected answer, the box next to this option is ticked 'YES' and the answer written freehand and left un-coded. The 'OTHER' option is also chosen if the subject answers 'YES' but does not know the specific answer. In cases where the subject is asked to list items and there is insufficient space, the most often used or the item the subject considered most important should be recorded.

Instructions for main questionnaire

Q1: These questions are intended to identify persons who have occasional and / or frequent **wheezing**. Subjects may confuse wheezing with snoring or bubbling sounds in the chest. 'Wheeze' can be described as 'A whistling sound, whether high or low pitched and however faint'. If the question is not understood, a vocal demonstration of wheezing by the interviewer can be helpful. No distinction is made between those who only wheeze during the day and those who only wheeze at night.

Q2: The question refers to waking with tightness in the chest at any time regardless of whether the subject has had a cold during that period.

Q3-Q5: These questions distinguish between attacks of breathlessness during periods of inactivity, 'exercise-induced' breathlessness and night-time (or during 'sleep period') breathlessness. In the question regarding breathlessness following activity, the word 'following' should be stressed. If the subject has not carried out any strenuous activity in the last 12 months for whatever reason, the answer is recorded as 'NO'. This includes those subjects who avoid strenuous activity because they would become breathless.

Supplementary questions have been added to question 5 to determine whether symptoms have been frequent in the last 3 months.

Q7-Q8: When night shift workers are interviewed the words 'on getting up' should be used instead of 'first thing in the morning'. A cough with their first smoke or on going out of doors is included. Clearing the throat or a single cough is excluded. The word 'usually' should be emphasised. An occasional cough may be considered as normal and the answer should be recorded as 'NO'. As a rough guide single coughs at a frequency of less than six a day are 'occasional'. The words 'do you cough like this' refers to whatever kind of cough or frequency of cough the subject has already reported in the previous question and whenever it occurred. 'Three months' refers to three consecutive months, and 'each year' to the last two years. There are special rules for recording the answers to question 7. If the answer to question 7 is doubtful, the interviewer should then ask question 8.1. The answer to question 8.1 is recorded as the answer to question 7. The interviewer should then ask question 8, followed by 8.1 again and the answers are recorded as they are given.

Q9-Q10: As with cough, phlegm with the first smoke or on going out of doors is included, but not mucoid discharge from the nose. Contrary to cough, however, 'occasional' phlegm production from the chest is considered abnormal if it occurs twice or more per day. The interviewer may use any suitable word that accords with local usage provided that it distinguishes phlegm from the chest or throat from pure nasal discharge. Some subjects admit to bringing up phlegm without admitting to coughing. This should be accepted without changing the replies to the questions about cough. Some people may claim

to cough up phlegm from the chest but tend to swallow them. This counts as a positive reply. For question 9, question 10.1 is used to ascertain the answer to question 9, as described above.

Q11: This question refers to any physical disability other than chest or heart disease (for example, confined to a wheelchair) that prevents the subject from walking normally, which has been present for at least 12 months. If the subject has a temporary physical disability that has not been present through the last 12 months, the questions are asked pertaining to the time when the subject was fit. If the subject is disabled from walking (e.g. confined to a wheelchair or uses crutches continuously) these questions are omitted and the disabling condition is recorded appropriately. 'Hurrying' implies walking quickly. These questions refer to the average condition during the previous two winters. If the subject avoids hurrying because they would become breathless and, therefore, the question is irrelevant, the answer recorded as 'NO'.

Q12: Further explanation of the definition of 'asthma' should not be given. If the term is not understood, the answer should be recorded as 'NO'.

Q12.2: If the subject does not remember their age at time of their first of most recent attack of asthma, the subject should give an answer based on his / her approximate estimate of age. This is more likely with the first, rather than the most recent, but an estimate may also be given for most 'recent attack'.

If the subject believes they have had asthma attacks 'since they were born' or their first attack was 'when they were a baby' the response should be coded as '01' years

Q12.3 If the most recent attack of asthma was 'when they were a baby' the response should be coded as '01' years

Q12.9: 'Currently taking medication' is defined as 'having the medication available at home'. Alternative therapy is included if prescribed by a licensed practitioner.

Q13: The term nasal allergy includes all symptoms of rhinitis, whether seasonal or perennial, and whatever the allergens associated with symptoms.

Q13.1 If the subject cannot remember how old they were when they first had hayfever or nasal allergy, then subject should give an approximate answer or 'best guess'.

Q14 These questions refer to nasal symptoms rather than diagnoses. Some subjects may respond yes to question 13 but no to question 14. In this case the question should be repeated and the response recorded but the interviewer should not influence the subject's response further.

Q14.1.2. The months of the year should be read out in turn and a yes no response recorded to each. A person who has symptoms throughout the year will answer yes twelve times.

Q14.1.3. Each potential aggravating factors should be read out and a no or yes response recorded. Subjects may not know what causes their symptoms in which case they are likely to answer no to all factors.

Q16. For steroid nasal sprays, each participating centre should make a list of the nasal drugs containing steroids that are used/available in their country for the treatment of nose problems. This list should be shown to the participant. If the interviewed person reports having used any of the medications on the list in the last 5 years, the answer is 'YES'.

Q16.2-16.4 Seasonal allergy is a common phenomenon among the general population. Therefore the intermittent use of nasal steroids is relatively common. The aim of this questions is to describe their pattern of use over the last five years. If a subject has taken nasal steroids **every** year for the preceding five years (responded yes to q16.2), they should complete q16.2.1 and then move onto question 17. For those who have not taken nasal steroids every year they should state how many years of the last 5 they have taken them (q16.3) and then give the average number of months each year they have used them (q 16.4). This may be difficult for subjects who have a highly variable use of nasal steroids but they should give their 'best guess'.

Q17: This question refers to antihistamines tablets, medicine, nasal sprays or eye drops and is structured in the same way as question 16. A list of all antihistamines commonly used or available in each centre should be made and shown to the participant. Subjects should provide information describing the pattern of use over the last 5 years. The rules guiding this are similar to those for question 16. Subjects should only respond 'YES' if they have used these medications for the treatment of their nasal disorder.

Clarify time frames

Q18: The question refers to 12 weeks of symptoms and the 12 weeks DO need to be consecutive.
Q19: This question refers to pain in a particular area of the head/face as shown in the picture. The question refers to 12 weeks of symptoms and the 12 weeks DO need to be consecutive.

Q20. Refers to discoloured nasal discharges (snot) refers to mucus produced in the nose, which has changed its original / usual colour. The time frame refers to 12 consecutive weeks during the last 12 months. The discoloured nasal discharges or mucus that we are asking for has to last for the mentioned time period. This excludes the nose blockage present during a common cold, which normally lasts for a shorter time period.

Q21.The question refers to 12 weeks of symptoms and the 12 weeks DO need to be consecutive
Q22.The question refers to 12 weeks of symptoms and the 12 weeks DO need to be consecutive

Q23 Participants should only respond 'yes' if a medically trained doctor has told them they have these conditions.

Q23.1-23.2. Some but not all participants may have had symptoms of their disease long before they were diagnosed with the condition. The answers to q23.1 and 23.2 may be different or the same.

Q23.3 This question states 'sinus problem' which includes both **sinusitis or nasal polyps**.

Q23.6 **Subjects who have had their adenoids removed as a child should respond 'NO' to this question**

Q24.2 The job that the subject believed made their eczema worse should be written down in full and coded using ISCO-88 4 digit coding.

Q24.3 If the precise cause of this problem is known to the subject the explanation as provided by the subject should be written clearly. Specifically the subject should identify any agents or chemicals that were identified as exacerbating their symptoms.

Q25. This question is asking about symptoms of a skin problem. Participants may respond negatively to this question even though they have reported they had eczema in question 24. The question should be repeated but the interviewer should not influence the participant's response further.

Q26. Difficulty breathing after taking medicines may occur for a variety of reasons. Participants can report up to two drugs as causing this problem. If more than two drugs have caused breathlessness, the two drugs which caused the most severe reactions should be coded (see coding scheme)

Q27.Nasal symptoms after taking medicines may occur for a variety of reasons. Participants can report up to two drugs as causing this problem. If more than two drugs have caused breathlessness, the two most recent drugs which caused the most severe reactions should be coded (see coding scheme). The same coding scheme as for q26 will be used.

Q28.Urticaria, nettle rash or hives after taking medicines may occur for a variety of reasons. Participants can report up to two most recent drugs as causing this problem. If more than two drugs have caused breathlessness, the two most recent drugs which caused the most severe reactions should be coded (see coding scheme). The same coding scheme as for q26 will be used.

Q29. These questions refer to a particular food intake or diet which might cause subject any illness or trouble. It could be any food. The subject should provide the name of this food. If more than three foods have been implicated those that cause the most severe or the most common reactions should be coded.

Some further questions

Q1. Subjects may need to use the 'best guess' to give their mothers age at the time they were born. If the subject does not know the response should be entered as '98' years

Q2. 'Hospitalised,' means spending a night as an inpatient in hospital. 'Lung disease' means any condition that was related to lower respiratory, chest or lung problems including chest infections, pneumonia and asthma.

Q3-Q4 The questions on parental smoking refer to whether the subject was environmentally exposed to cigarette smoke during childhood (up to 14 years). If the subject did not live with his biological father/mother, the interviewer should substitute male / female guardian. Maternal smoking during pregnancy refers to the natural mother. The definition of a smoker is that given in question 26.

Q6-Q7.These questions refer to subject's biological brother and sisters. The questions regarding numbers of brothers and sisters and their symptoms are to identify atopic siblings. Half-brothers and half-sisters do not count as siblings. The words 'older' and 'younger' should be stressed. If the subject has a twin, these are to be counted conventionally as 'younger'. The word 'other' should be stressed to identify siblings who have, or have had, allergic symptoms like hay fever but did not have asthma.

Q8-Q11.These questions refer to subject's biological mother and father's history of asthma, eczema, skin, nasal allergy or hay fever.

Q12. These questions are intended to identify childhood exposure to infectious disease, which is most likely to occur when a child is in contact with other children and older children. The interviewer should stress the word 'older.' 'Regularly' sharing a bedroom with other children means routinely at home for more than one year as opposed to when visiting relatives or short holiday periods. The answer is restricted to older children.

Q13. Local terminology relevant to day care for children under five years can be used. If a child is looked after by a childminder or 'day-mother', together with children from other families this is considered to be 'day-care'.

Q14. 'Serious' respiratory infections include bronchitis, whooping cough, pneumonia or any infection considered serious by the subject.

Q15-Q16. These questions are about pets in the home when the subject was a child.

Q17. This question describes the place where subject lived most of the time when under the age of five years.

Work and education

Q18-18.1 A full-time student is defined as one currently attending an educational establishment and not having full-time employment. If the subject is a student, but works part-time this counts as full-time education.

Q18.4 The first job is a job held for more than three consecutive months and more than 8 hours per week.

Q18.5 Details of this job should be provided with as much detail as possible to facilitate coding.

Q18.6 Refers to the job described in the response to q18.5

Q18.9 Details of this job should be provided with as much detail as possible to facilitate coding.

Q19. If the subject is not sure about work-related respiratory problems, no elaboration should be made and a negative answer recorded.

Q21. If subjects are not sure about exposure to vapours or fumes in the work-place, the answer is recorded as 'NO'.

Q21.1Details of this job should be provided with as much detail as possible to facilitate coding.

Q22. Note that this question deals about exceptional situations, typically accompanied by exposure to high levels of vapour, gas, dust or fumes. We are interested in spills / leaks / accidents, either at work or elsewhere. If subject doesn't know or has doubts, no elaboration should be made and a negative answer recorded.

Q23.1 Details of this job should be provided with as much detail as possible to facilitate coding.

Environment

Q24.The number of cars passing the home is an **average** during daylight hours. For people who live on roads where traffic flow varies substantially during the day (e.g.: excess flow during the rush hour) this may be difficult. They should make a 'best guess'. Subjects may find it useful to consider that 80 per hour is equivalent to one car every 45 seconds.

Q25. The number of buses/trucks passing the house is an **average** during daylight hours. For people who live on roads where traffic flow varies substantially during the day (e.g.: excess flow during the rush hour) this may be difficult. They should make a 'best guess'. Subjects may find it useful to consider that 20 per hour is equivalent to one bus/truck every three minutes.

Tobacco and Alcohol

Q26.1 If the subject was not able to report how old he/she was when he/she started smoking the interviewer should ask for an approximate age.

Q26.2 The question on 'present' smoking statues relates to the last month. For example, if the subject smoked their last cigarette two weeks ago the answer is 'YES'. The emphasis should be placed on of **one month ago.**

Q26.2 The participants should now describe their current smoking frequency. 'Self-rolled,' cigarettes are included in the number of cigarettes smoked. The question on 'pipe tobacco' are to be answered in either ounces or grams, depending on which the subject is most familiar with.

Q26.3 If the subject's smoking habit has changed, they will be asked at what age their smoking habit changed. The tendency will be to remember 'how long ago' rather than 'at what age', so the interviewer will need to work out with the subject the age at cutting down.

Q26.3.2 The questions are designed so that a consistent smoker answers only about what he/she smokes now and ex-smoker answers about what he/she now smokes and what he/she smoked before. The subject will be asked regarding his / her entire smoking habit / pattern before cutting down or stopped smoking. 'Self-rolled,' cigarettes are also included in the number of cigarettes smoked.

Q26.4 The question on inhalation of smoke refers to the way subject's smoke for most of the time.

Q27. The question on regular exposure to smoking is concerned with exposure to environmental tobacco smoke and related to the last 12 months only. The question may be irrelevant (biologically) to a present smoker, but should still be asked.

Q27.1 People in the household (apart from the subject) who smoke regularly may include a babysitter/nanny or housekeeper/au pair, who are present most of the time or live in. It also includes regular visitors who smoke in the house at least five days a week. It does not include occasional visitors who smoke.

Q27.2 If the subject works in a very large room (open planned office or factory) where people smoke some distance away, 10m (3ft) can be regarded as a cut-off.

Q27.3 In order to obtain more information on the location, in which people are exposed to tobacco smoke, subjects are asked at what locations they have experienced their exposures. 'Elsewhere' may include the home of relatives or home of friends.

Q28.This refers to subject's pattern of alcohol consumption.

Q29-Q31.The subject should be asked to bring along any medication that he/she is currently taking. The question refers to the last 12 months; so it is possible that the subject may no longer have the medicine or that it is not in its original container. Therefore, the interviewer can also show the subject photographs of inhalers/medicines at the time of questioning.

Of two or more inhalers or medicines from the same group are simultaneously used, the one that is most often or most recently used should be recorded.

The subject is required to describe the average number of puffs of a short acting beta-agonist, long acting beta-agonist, anti-muscarinic and inhaled steroids. However the DOSE of inhaled steroids only will be calculated and only drugs containing long acting beta2 agonists or inhaled steroids will be coded.

If a subject is taking an inhaled medicine that contains both a steroid and a long acting beta 2 agonist this medication should be coded (q29.2.2). However in question 29.4.1 the coding for this medicine should also be inserted. The coding lists are provided and the code provided depends on the dose contained in the product. If a medicine for which no coding appears is being used fieldworkers should email d.jarvis@imperial.ac.uk, labelling the email as steroid coding query and giving the details of the medication. The coding system is provided but 'local examples (last column) may vary between centres)

Subjects taking inhaled steroids should provide sufficient information to complete q 29.4.

Q30. The medications include those used in the last 12 months and are those that are used to 'help with breathing' only.

Q31.This question refers to inhaled steroids and is structured in the same way as question 16 and 17 (first section). A list of all inhaled steroids commonly used or available in each centre should be made and shown to the participant. Subjects should provide information describing the pattern of use over the last 5 years. The rules guiding this are similar to those for question 16.

Use of health services

Q32. These questions refer to desensitisation injections or immunotherapy. The subject may participant this information. If the question is not understood, the answer is recorded as 'NO'. Desensitisation injections should be distinguished from other injections to 'help breathing', which can include penicillin shots in acute respiratory infection or depot steroids.

Q33. This question is to ascertain whether a hospital casualty attendance due to breathing problems has occurred in the last year. 'Breathing problems' means any condition that was related to lower respiratory, chest or lung problems including chest infections, pneumonia and asthma.

Q33.1.1 A more specific reason for attendance is provided. No explanation of the terms should be given.

Q33.1.2 Refers to the number of times the subject has attended casualty for breathing problems.

Q35. This question is asking subject whether they have seen a medically qualified doctor. 'Breathing problems' means any condition that was related to lower respiratory, chest or lung problems including chest infections, pneumonia and asthma.

Last but not least the interviewer should document how the interview was conducted and enter their appropriate fieldworker identification number for data query tracking purposes.

Some further question

Q5 Countries and Territories

001	Afghanistan	063	Dominica
002	Albania	064	Dominican Republic
003	Algeria	065	Ecuador
004	American Samoa	066	Egypt
005	Andorra	067	El Salvador
006	Angola	068	Equatorial Guinea
007	Anguilla	069	Estonia
008	Antarctica (Australian Territory)	070	Ethiopia
009	Antigua & Barbuda	071	Falkland Islands
010	Antilles (Netherlands)	072	Faroe Islands
011	Argentina	073	Fiji
012	Armenia	074	Finland
013	Ascension Island	075	France
014	Australia	076	French Guinea
015	Austria	077	French Polynesia
016	Azerbaijan	078	Gabon
017	Azores	079	Gambia
018	Bahamas	080	Germany (former East)
019	Bahrain	081	Germany (former West)
020	Bangladesh	082	Georgia
021	Barbados	083	Ghana
022	Belgium	084	Gibraltar
023	Belize	085	Greece (Mainland)
024	Benin	086	Greek Islands
025	Bermuda	087	Greenland
026	Bhutan	088	Grenada
027	Bolivia	089	Guadeloupe
028	Botswana	090	Guam
029	Brazil	091	Guatemala
030	British Virgin Island	092	Guinea-Bissau
031	Brunei	093	Guinea

032	Bulgaria
033	Burkina Faso
034	Burma
035	Burundi
036	Byelorussia
037	Cameroon
038	Canada
039	Canary Islands
040	Cape Verde
041	Caroline Islands
042	Cayman Islands
043	Central African Republic
044	Chad
045	Channel Islands
046	Chatham Islands
047	Chile
048	China and Taiwan
049	Christmas Island
050	Cocos (Keeling Island)
051	Colombia
052	Comoros
053	Congo
054	Cook Islands
055	Corsica
056	Costa Rica
057	Cote d'Ivoire (Ivory Coast)
058	Cuba
059	Cyprus
060	Czechoslovakia
061	Denmark
062	Dijbout
125	Liechtenstein
126	Lithuania
127	Luxembourg
128	Macao
129	Madagascar
130	Madeira
131	Malawi
132	Malaysia
133	Maldives
134	Mali
135	Malta
136	Marshall Island
137	Martinique
138	Mauritiana
139	Mauritius
140	Mexico
141	Micronesia (Federated States of)
142	Midway Islands
143	Moldavia
144	Monaco
145	Mongolia
146	Montserrat
147	Morocco
148	Mozambique
149	Namibia
150	Nauru
151	Nepal
152	Netherlands
153	New Caledonia
094	Guyana
095	Haiti
096	Honduras
097	Hong Kong
098	Hungary
099	Iceland
100	India
101	Indonesia
102	Iran
103	Iraq
104	Irish Republic
105	Israel and occupied territory
106	Italy (includes Vatican City)
107	Jamaica
108	Japan
109	Johnston and Sand Island
110	Jordan
111	Kampuchea (Cambodia)
112	Kazakhstan
113	Kenya
114	Kirghizia
115	Kiribati
116	Korea (North)
117	Korea (South)
118	Kuwait
119	Laos
120	Latvia
121	Lebanon
122	Lesotho
123	Liberia
124	Libya
188	Saudi Arabia
189	Senegal
190	Seychelles
191	Sierra Leone
192	Singapore
193	Solomon Islands
194	Somalia
195	South Africa
196	Spain
197	Sri Lanka
198	Sudan
199	Suriname
200	Swaziland
201	Sweden
202	Switzerland
203	Syria
204	Tadzhikistan
205	Tanzania
206	Thailand
207	Togo
208	Tonga
209	Trinidad and Tobago
210	Tristan de Cunha
211	Tunisia
212	Turkey
213	Tukmenistan
214	Turks and Caicos Island
215	Tuvalu
216	Uganda

154	New Zealand
155	Nicaragua
156	Niger
157	Nigeria
158	Niue Island
159	Norfolk Island
160	North Miriana Island
161	Norway
162	Oman
163	Pakistan
164	Palau
165	Panama
166	Papua New Guinea
167	Paraguay
168	Peru
169	Philippines
170	Pitcairn Islands
171	Poland
172	Portugal
173	Puerto Rico
174	Qatar
175	Reunion
176	Rodriguez Island
177	Romania
178	Russia (see also other States)
179	Rwanda
180	St Christopher and Nevis
181	St Helena and Dependencies
182	St Lucia
183	St Pierre and Miquelon
184	St Vincent and the Grenadines
185	San Marino
186	Sao Tome Principe
187	Sardinia
217	Ukraine
218	United Arab Emirates
219	United Kingdom (England IOM)
220	United Kingdom (Scotland)
221	United Kingdom (Wales)
222	United Kingdom (N Ireland)
223	Uruguay
224	USA
225	Uzebikstan
226	Vanuatu
227	Venezuela
228	Vietnam
229	Virgin Islands of the US
230	Wake Island
231	Wallis and Future Island
232	Western Sahara
233	Western Somoa
234	Yemen Arab Republic
235	Yemen (Peoples Democratic Republic)
236	Yugoslavia (Former)
237	Zaire
238	Zambia
239	Zimbabwe
998	Not coded

Q26- Q28 Drugs causing breathlessness, nasal and skin problems

01	Aspirin or aspirin containing product
02	Other non-steroidal anti-inflammatory drug (eg ibuprofen)
03	Paracetamol or paracetamol containing drug
10	Beta – blocker
20	Penicillin or penicillin like drugs unspecified
21	Aminoglycoside e.g.
22	Betalactam antibiotics
23	Caphalosporins
24	Other Antibiotics
30	Radiocontrast media
40	Local anaesthetics
98	Don’t know the type or name of drug

Q29. Coding list for foods causing allergy

01 Almond	37 Garlic	72 Pumpkin
02 Apple	38 Gooseberry	73 Radish
03 Apricot	39 Grape	74 Raspberry
04 Artichoke	40 Grapefruit	75 Rhubarb
05 Asparagus	41 Hazelnut	76 Rice
06 Aubergine	42 Herring	77 Rye
07 Avocado	43 Kiwi	78 Salmon
08 Banana	44 Lamb	79 Shrimp (Prawn)
09 Barley	45 Leek	80 Soya
10 Beans (butter)	46 Lemon	81 Spinach
11 Beans (green)	47 Lime	82 Strawberry
12 Beans (red, kidney)	48 Lobster	83 Swede
13 Beef	49 Lychee	84 Tomato
14 Blackberries	50 Malt	85 Tuna
15 Blue mussel	51 Mango	86 Veal
16 Brazil nut	52 Melon	87 Walnut
17 Broccoli	53 Milk (cows)	88 Watercress
18 Brussels sprouts	54 Oat	89 Wheat (Flour, Gluten)
19 Buckwheat	55 Onion	90 Yam
20 Cabbage	56 Orange	91 Yeast (bakers)
21 Cacao	57 Oyster	92 Yoghurt
22 Carrot	58 Papaya	93 mustard seed
23 Cauliflower	59 Parsley	94 sesame seed
24 Celery	60 Passion fruit	95 lentils
25 Cheese (hard)	61 Pea	96 sunflower seed
26 Cheese (soft)	62 Peach	97 poppy seed
27 Cherry	63 Peanut	98 not coded
28 Chocolate	64 Pear	99 not known
29 Coconut	65 Pecan	100 nuts not specified
30 Corn	66 Pepper (red/green)	101 vegetables not specified
31 Crab	67 Pineapple	102 fish not specified
32 Date	68 Plum	103 fruit not specified
33 Egg	69 Pork	104 dairy not specified
34 Fig	70 Potato	
35 Fish (oily, Sardine)	71 Poultry (Chicken, Turkey, Duck)	
36 Fish (white, Cod, Plaice)		

Shellfish is defined as:

Crab
Crayfish
Langust (spiny lobster)
Lobster
Shrimp

Molluscs are defined as:

Abalone
Clam
Cockle
Cuttle-fish
Mussel
Oyster
Scallop
Snail
Squid
Winkle

Q29.2 and Q29.4 Inhaled Steroids with or without beta-agonists

	Inhaled Steroids	**Dose**
01	Beclomethasone (beclometasone) e.g.; AeroBec Autohaler /QVar	50ug/puff
02	Beclomethasone (beclometasone) AeroBec Clickhaler / QVar	100ug/puff
03	Beclomethasone (beclometasone) eg; Becotide	200ug/puff
04	Beclomethasone (beclometasone) eg; Aerobec Forte	250ug/puff
05	Beclomethasone (beclometasone)	400ug/puff
10	Budesonide eg: Pulmicort	50ug/puff
11	Budesonide eg: Turbohaler	80 ug puff
12	Budesonide eg: Pulmicort Turbohaler	100ug/puff
13	Budesonide eg: Pulmicort	160 ug puff
14	Budesonide	200ug/puff
15	Budesonide eg: Symbicort 80	250ug/puff
16	Budesonide eg: Cyclohaler	320ug puff
17	Budesonide	400ug puff
20	Fluticasone eg: Accuhaler 25)	25ug/puff
21	Fluticasone eg: Accuhaler	50ug/puff
22	Fluticasone eg: Accuhaler	100 ug/puff
23	Fluticasone eg: Accuhaler 125)	125ug/puff
24	Fluticasone	250 ug/puff
25	Fluticasone	500 ug/puff
30	Ciclesonide Aerosol Inhalation	80ug/puff
35	Momentasone Twisthaler	200ug/puff
90	Unknown/not provided	

(Need names and doses of other steroids)

Appendix 20
Food frequency Questionnaire

Participant's ID	
Centre ID	

GA²LEN FOLLOW-UP STUDY

Food Frequency Questionnaire

GLOBAL ALLERGY AND ASTHMA EUROPEAN NETWORK

NETWORK OF EXCELLENCE

This questionnaire asks for background information related to what you eat. Your answers will be treated as strictly confidential and will be used only for the purposes of this research.

GLOBAL ALLERGY AND ASTHMA EUROPEAN NETWORK

Dear Participant - Please fill in the following boxes:

Date today DD/MM/YYYY	Date of birth DD/MM/YYYY	Indicate whether a female or male

Dear Participant:

In the context of the GA^{2}LEN Network, we would like to ask you to complete and return this food frequency questionnaire (FFQ). Please tick (√) in the box to indicate how often, on average, you have eaten the specified amount of each food during the last 12 months. Do not tick more than one box per food.

- Because this FFQ is being used in several countries, YOU WILL BE UNFAMILIAR WITH some of the foods listed in this questionnaire. If you do not eat some of these, please tick the option "Rarely/never".
- If you make a mistake and put a tick in the wrong box just cross through the tick as shown below, and put a tick in the correct box.

EXAMPLE

Vegetables excluding potatoes (medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
Lettuce			√	~~√~~			

- PLEASE TICK **<u>ONE BOX ONLY</u>** PER LINE AND DO NOT LEAVE FOODS WITHOUT ANSWER.

- For seasonal fruits such as strawberries or grapes, if you eat them about once a week when in season, you should put a tick in the column "once a week".

We thank you very much for your collaboration.
GA^{2}LEN Nutrition Team

Tick one box for every food to show how often you ate it. Please answer every question, if you are uncertain about how to answer a question then do best you can, but please do not leave a question blank.

1. Bread and rolls (one slice or medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q1p1 Total bread (any, on average)	1	2	3	4	5	6	7
q1p2 Wholemeal or brown bread (with or without seeds)	1	2	3	4	5	6	7
q1p3 White bread (e.g. baguette, rolls, sliced crust(less))	1	2	3	4	5	6	7
q1p4 Rye bread (any)	1	2	3	4	5	6	7
q1p5 Kneipp bread (dark/ light)	1	2	3	4	5	6	7
q1p6 Nan, Paratha	1	2	3	4	5	6	7
q1p7 Chapatti	1	2	3	4	5	6	7
q1p8 Wheat or yeast rusks	1	2	3	4	5	6	7

2. Breakfast cereals (any) (medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q2 Any breakfast cereals (e.g. oatmeal, wheat germ, cornflakes, Quaker, kasha)	1	2	3	4	5	6	7

3. Semolina (table spoon)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q3 Couscous or semolina	1	2	3	4	5	6	7

4. Pasta (and wheat derived foods) (medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q4p1 Any pasta (on average)	1	2	3	4	5	6	7
q4p2 Plain (refined) pasta (e.g. spaghetti, macaroni)	1	2	3	4	5	6	7
q4p3 Plain wholemeal (unrefined) pasta	1	2	3	4	5	6	7
q4p4 Filled pasta (with meat/cheese/vegetables)	1	2	3	4	5	6	7
q4p5 Noodles (excluding rice noodles)	1	2	3	4	5	6	7
q4p6 Xilopites	1	2	3	4	5	6	7

5. Bakery products (one biscuit, one unit, or medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q5p1 Any cakes or pastries (on average)	1	2	3	4	5	6	7
q5p2 Cakes (e.g. sponge, gateau, chocolate, ginger, honey, apple)	1	2	3	4	5	6	7
q5p3 Danish pastries (e.g. croissants, wienerbrød, cornetti, brioche)	1	2	3	4	5	6	7
q5p4 Sweet rolls (ensaymadas), with/without stuffing	1	2	3	4	5	6	7
q5p5 Muffins (Magdalenas)	1	2	3	4	5	6	7
q5p6 Doughnuts, buns (plain or filled)	1	2	3	4	5	6	7
q5p7 Pudding and desserts: cheese cake, rice pudding, spotted dick	1	2	3	4	5	6	7
q5p8 Custard cream	1	2	3	4	5	6	7
q5p9 Greek cakes (Baklavas, Kandaifi, Galaktoboureko, Revani, Karidopita)	1	2	3	4	5	6	7
q5p10 Pancakes (including griddle cakes)	1	2	3	4	5	6	7
q5p11 Italian-style biscuits (e.g. biscotti) or Greek Paximadia	1	2	3	4	5	6	7
q5p12 Plain biscuits (e.g. digestives)	1	2	3	4	5	6	7
q5p13 Crisp fried cakes (faworki)	1	2	3	4	5	6	7
q5p14 Thin biscuits (e.g. crackers, knackerbrod, rice-wafer, pretzel)	1	2	3	4	5	6	7
q5p15 Sweet/flavoured biscuits (including creamy biscuits)	1	2	3	4	5	6	7

6. Rice (1 cup (cooked))	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q6p1 Rice (any)	1	2	3	4	5	6	7
q6p2 White rice	1	2	3	4	5	6	7
q6p3 Brown/wholemeal (unrefined) rice	1	2	3	4	5	6	7
q6p4 Rice noodles	1	2	3	4	5	6	7

7. Sugar (tea spoon) & jam (enough for 1 slice of bread)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q7p1 Table sugar	1	2	3	4	5	6	7
q7p2 Jam	1	2	3	4	5	6	7
q7p3 Marmalade	1	2	3	4	5	6	7
q7p4 Honey	1	2	3	4	5	6	7
q7p5 Syrup spreads	1	2	3	4	5	6	7
q7p6 Apple spread (e.g. Dutch Appel Stroop)	1	2	3	4	5	6	7

8. Sugar products excluding chocolate (one unit)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q8p1 Total sweets (or Godis) or bonbons	1	2	3	4	5	6	7
q8p2 Boiled sweets, toffees, caramels, filled confetties	1	2	3	4	5	6	7
q8p3 Mixed candies	1	2	3	4	5	6	7
q8p4 Cereal bars, flapjacks/fruit bar	1	2	3	4	5	6	7
q8p5 Halva (e.g. semolina/sesame)	1	2	3	4	5	6	7
q8p6 Water ice (lolly ice)	1	2	3	4	5	6	7

9. Chocolate	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q9p1 Chocolates (any)	1	2	3	4	5	6	7
q9p2 Chocolate snack bars, e.g. Mars, Crunchie (1 bar)	1	2	3	4	5	6	7
q9p3 Chocolate (e.g. plain, dark/milk) (a square or 50g)	1	2	3	4	5	6	7

10. Vegetable oils (1 table spoon)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q10p1 Vegetable oil (blended, any)	1	2	3	4	5	6	7
q10p2 Sunflower oil	1	2	3	4	5	6	7
q10p3 Olive oil	1	2	3	4	5	6	7

11. Margarine and lipids of mixed origin (1 table spoon)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q11p1Any margarine or spread (excluding soya spread)	1	2	3	4	5	6	7
q11p2 Low-fat margarine (up to 30% fat)	1	2	3	4	5	6	7
q11p3 Half-fat margarine (~40 to 60% fat)	1	2	3	4	5	6	7
q11p4 Normal margarine (≥70% fat)	1	2	3	4	5	6	7
q11p5 Blended spreads (excluding soya)	1	2	3	4	5	6	7
q11p6 Soya-based spreads (any)	1	2	3	4	5	6	7

12. Butter and animal fats (amount spread enough to cover a loaf of bread)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q12p1 Any butter	1	2	3	4	5	6	7
q12p2 Low-fat butter (less than 40% fat)	1	2	3	4	5	6	7
q12p3 Half-fat butter (~40 to 60% fat)	1	2	3	4	5	6	7
q12p4 Normal butter (≥ 70% fat)	1	2	3	4	5	6	7

13. Nuts (10 units approx.)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q13p1 Any nuts	1	2	3	4	5	6	7
q13p2 Peanuts	1	2	3	4	5	6	7
q13p3 Cashew nuts	1	2	3	4	5	6	7
q13p4 Nut-based spread (e.g. Nutella) (1 teaspoon)	1	2	3	4	5	6	7

14. Legumes (1 cup (cooked))	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q14p1Any legumes	1	2	3	4	5	6	7
q14p2 Kidney (red), black beans	1	2	3	4	5	6	7
q14p3 Lentils	1	2	3	4	5	6	7
q14p4 Chickpeas (including hummus)	1	2	3	4	5	6	7
q14p5 Cluster beans (guar)	1	2	3	4	5	6	7

Legumes *(continued)* (1 cup cooked)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q14p6 French beans (string beans)	1	2	3	4	5	6	7
q14p7 Fava beans	1	2	3	4	5	6	7
q14p8 Soya beans	1	2	3	4	5	6	7

15. Vegetables excluding potatoes (medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q15p1 Any vegetables (excluding potatoes)	1	2	3	4	5	6	7
q15p2 Lettuce	1	2	3	4	5	6	7
q15p3 Spinach (including lamb's quarters)	1	2	3	4	5	6	7
q15p4 Chard	1	2	3	4	5	6	7
q15p5 Fenugreek	1	2	3	4	5	6	7
q15p6 Wild greens (e.g. amaranth, purslane, watercress)	1	2	3	4	5	6	7
q15p7 Taro (Arvi)	1	2	3	4	5	6	7
q15p8 Okra	1	2	3	4	5	6	7
q15p9 Caper	1	2	3	4	5	6	7
q15p10 Tomato	1	2	3	4	5	6	7
q15p11 Aubergine (including melitzanolsalata)	1	2	3	4	5	6	7
q15p12 Courgette	1	2	3	4	5	6	7
q15p13 Sweet peppers (e.g. red, green, yellow)	1	2	3	4	5	6	7
q15p14 Cucumber	1	2	3	4	5	6	7
q15p15 Bitter melon (Karela)	1	2	3	4	5	6	7
q15p16 Carrots	1	2	3	4	5	6	7
q15p17 Parsnip	1	2	3	4	5	6	7
q15p18 Turnip or Swede	1	2	3	4	5	6	7
q15p19 Artichokes	1	2	3	4	5	6	7
q15p20 Radish	1	2	3	4	5	6	7
q15p21 Beetroot	1	2	3	4	5	6	7
q15p22 Celery	1	2	3	4	5	6	7
q15p23 Coleslaw	1	2	3	4	5	6	7
q15p24 Sweet Corn	1	2	3	4	5	6	7

Vegetables excluding potatoes *(continued)* (medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q15p25 Asparagus	1	2	3	4	5	6	7
q15p26 Herbs (e.g. mint, fennel, chive, basil, dill, coriander, parsley) (1 table spoon)	1	2	3	4	5	6	7
q15p27 Leek	1	2	3	4	5	6	7
q15p28 White/other mushrooms	1	2	3	4	5	6	7
q15p29 Onion	1	2	3	4	5	6	7
q15p30 Garlic	1	2	3	4	5	6	7
q15p31 Cauliflower	1	2	3	4	5	6	7
q15p32 Pumpkin	1	2	3	4	5	6	7
q15p33 Brussels sprouts	1	2	3	4	5	6	7
q15p34 Broccoli	1	2	3	4	5	6	7
q15p35 Cabbage (e.g. white, green red, Savoy)	1	2	3	4	5	6	7
q15p36 Stuffed vegetables (e.g. dolmas, vine/green leaves with rice or meat)	1	2	3	4	5	6	7
q15p37 Pickled vegetables (e.g. cucumber, radish, cabbage)	1	2	3	4	5	6	7
q15p38 Ginger (e.g. in savoury and sweet dishes, in infusion)	1	2	3	4	5	6	7

16. Starchy roots or potatoes (medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q16p1 Potatoes (on average, in all forms)	1	2	3	4	5	6	7
q16p2 Mashed potatoes	1	2	3	4	5	6	7
q16p3 Baked/roasted/casserole	1	2	3	4	5	6	7
q16p4 Chips/French fries	1	2	3	4	5	6	7
q16p5 In salads	1	2	3	4	5	6	7
q16p6 Potato dumpling, bread dumpling, gnocchi	1	2	3	4	5	6	7
q16p7 Potato tortilla (omelette)	1	2	3	4	5	6	7
q16p8 Sweet potato	1	2	3	4	5	6	7

17. Fruits (one piece of fruit)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q17p1 Fresh fruits (any)	1	2	3	4	5	6	7
q17p2 Apple	1	2	3	4	5	6	7
q17p3 Pear	1	2	3	4	5	6	7
q17p4 Banana	1	2	3	4	5	6	7
q17p5 Peach	1	2	3	4	5	6	7
q17p6 Pineapple	1	2	3	4	5	6	7
q17p7 Cherries (1 cup)	1	2	3	4	5	6	7
q17p8 Rhubarb	1	2	3	4	5	6	7
q17p9 Forest fruits - Berries (e.g. blueberry, strawberry, blackcurrants, blackberry raspberry) (1 cup)	1	2	3	4	5	6	7
q17p10 Melon/ Watermelon	1	2	3	4	5	6	7
q17p11 Grape	1	2	3	4	5	6	7
q17p12 Mango	1	2	3	4	5	6	7
q17p13 Apricot	1	2	3	4	5	6	7
q17p14 Nectarine	1	2	3	4	5	6	7
q17p15 Plum	1	2	3	4	5	6	7
q17p16 Squeezed fresh fruit	1	2	3	4	5	6	7
q17p17 Pineapple	1	2	3	4	5	6	7
q17p18 Kiwi	1	2	3	4	5	6	7
q17p19 Lemon	1	2	3	4	5	6	7
q17p20 Orange	1	2	3	4	5	6	7
q17p21 Mandarin/Tangerine	1	2	3	4	5	6	7
q17p22 Grapefruit	1	2	3	4	5	6	7
q17p23 Canned fruits (any, 1 can)	1	2	3	4	5	6	7
q17p24 Raisin, sultana (1 table spoon)	1	2	3	4	5	6	7
q17p25 Fig	1	2	3	4	5	6	7
q17p26 Prune	1	2	3	4	5	6	7
q17p27 Olives (e.g. black, green) (5 units)	1	2	3	4	5	6	7

18. Fruit juices (1 glass 200 ml)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q18p1 Concentrated juice, with sugar	1	2	3	4	5	6	7
q18p2 Concentrated juice, without sugar	1	2	3	4	5	6	7

19. Non-alcoholic beverages (1 glass 200ml)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q19p1 Carbonated/soft/isotonic drinks	1	2	3	4	5	6	7
q19p2 Tap water	1	2	3	4	5	6	7
q19p3 Mineral water (e.g. still or sparkling)	1	2	3	4	5	6	7
q19p4 Soda/coke with sugar	1	2	3	4	5	6	7
q19p5 Soda/coke without sugar	1	2	3	4	5	6	7

20. Tea/coffee (1 cup)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q20p1 Black tea (any)	1	2	3	4	5	6	7
q20p2 Coffee (instant or ground)	1	2	3	4	5	6	7
q20p3 Greek (Turkish) Coffee	1	2	3	4	5	6	7
q20p4 Herbal tea/infusions (e.g. camomile, jasmine)	1	2	3	4	5	6	7

21. Beer (1/2 pint or 1 glass 200 ml)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q21 Beer (any)	1	2	3	4	5	6	7

22. Wine (1 glass125 ml)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q22p1 Any wine	1	2	3	4	5	6	7
q22p2 Red wine	1	2	3	4	5	6	7
q22p3 White wine	1	2	3	4	5	6	7
q22p4 Rose wine	1	2	3	4	5	6	7

23. Other alcoholic beverages (1 glass 50 ml)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q23p1 Fortified wines (Liqueurs) (e.g. Sherry, port, Madeira)	1	2	3	4	5	6	7
q23p2 Spirits (e.g. whisky, vodka, rum, gin)	1	2	3	4	5	6	7

24. Red meat and meat products (medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q24p1 Any red meat (e.g. beef, veal, lamb, pork, game)	1	2	3	4	5	6	7
q24p2 Hot/cold roast beef, boiled beef, beef steak, fillet, loin	1	2	3	4	5	6	7
q24p3 Beef burger	1	2	3	4	5	6	7
q24p4 Minced beef meat (e.g chilli con carne, Bolognese sauce, meatballs, hakkebof, karbonader)	1	2	3	4	5	6	7
q24p5 Meat stew, casserole, in curry	1	2	3	4	5	6	7
q24p6 Pork cutlet, chop, steak, fillet, loin, pork ribs	1	2	3	4	5	6	7
q24p7 Meat pies (any, e.g. Cornish pasties, steak & kidney)	1	2	3	4	5	6	7
q24p8 Sausages (e.g. blood sausage, pressack, embuchado, lyoner, jagdwurst, mettwurst)	1	2	3	4	5	6	7
q24p9 Spreadable sausage (e.g. teewurst)	1	2	3	4	5	6	7
q24p10 Veal	1	2	3	4	5	6	7
q24p11 Small game (e.g. rabbit, goat, pheasant, duck)	1	2	3	4	5	6	7
q24p12 Other game (e.g. deer, moose)	1	2	3	4	5	6	7
q24p13 Lamb (e.g. in stews, kebabs)	1	2	3	4	5	6	7
Smoked/cured meat (1 slice)							
q24p14 Cured pork (cold or hot-cooked)	1	2	3	4	5	6	7
q24p15 Salami, gammon, ham (e.g. Serrano, prosciutto)	1	2	3	4	5	6	7

Smoked/cured meat (1 slice or a medium serving) *(continued)*	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q24p16 Frankfurter (e.g. wienerle, bockwurst, knackwurst)	1	2	3	4	5	6	7
q24p17 Bacon, bacon cubes	1	2	3	4	5	6	7
q24p18 Smoked lamb (e.g hangikjot)	1	2	3	4	5	6	7
q24p19 Smoked game (any)	1	2	3	4	5	6	7

25. Poultry (medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q25p1 Any poultry	1	2	3	4	5	6	7
Fresh (un-smoked)							
q25p2 Chicken, boiled, roasted	1	2	3	4	5	6	7
q25p3 Chicken in stews, breadcrumbs, pies, fricassee, etc	1	2	3	4	5	6	7
q25p4 Turkey, roasted, boiled, strips, etc	1	2	3	4	5	6	7
q25p5 Turkey in stews, breadcrumbs, pies, etc.	1	2	3	4	5	6	7
Smoked or cured poultry							
q24p6 Any smoked/cured poultry	1	2	3	4	5	6	7

26. Offal (medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q26p1 Liver, pates, potted meat (Rilletes)	1	2	3	4	5	6	7
q26p2 Other offal (e.g. tongue, brain, heart, kidney, tripe, chitterlings)	1	2	3	4	5	6	7

27. Fish and seafood (medium serving)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q27p1 Any fish (fresh, tinned, smoked, fatty, white)	1	2	3	4	5	6	7
q27p2 Fresh fatty fish (e.g. salmon, tuna, trout, anchovy, herring, mackerel, sardine, gravalex, eel)	1	2	3	4	5	6	7

Fish and seafood (medium serving) ***(continued)***	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q27p3 Fresh white fish (e.g. hake/burbot, cod, haddock, plaice, whiting)	1	2	3	4	5	6	7
q27p4 Other fresh fish/seafood products (e.g. fish roe, taramasalata)	1	2	3	4	5	6	7
q27p5 Fresh Crustaceans and molluscs (e.g. mussel, crab, calamari, octopus, cuttlefish, shrimp, clam)	1	2	3	4	5	6	7
q27p6 Cured or smoked fatty fish (e.g. sardines, tuna, salmon, kipper)	1	2	3	4	5	6	7
q27p7 Cured or smoked white fish (e.g. cod, bacalhau)	1	2	3	4	5	6	7
q27p8 Tinned fatty fish (e.g. sardines, tuna, salmon)	1	2	3	4	5	6	7
q27p9 Tinned crustaceans and molluscs (e.g. mussel, crab, calamari, octopus, cuttlefish, shrimp, clam)	1	2	3	4	5	6	7

28. Eggs (chicken) (1 egg)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q28p1 Eggs (any, on average)	1	2	3	4	5	6	7
q28p2 Eggs (fried/poached/boiled/hard boiled/in sandwiches)	1	2	3	4	5	6	7
q28p3 Egg-based savoury dishes (e.g. omelettes, banitsa)	1	2	3	4	5	6	7
q28p4 Egg-based desserts (e.g. Egg cakes, egg custard tarts, egg and nuts sweets)	1	2	3	4	5	6	7

29. Milk (cow) & soya (1 glass/200ml)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q29p1 Total milk (any, excluding soya)	1	2	3	4	5	6	7
q29p2 Sour milk (alone/with fruits)	1	2	3	4	5	6	7
q29p3 Full-fat milk	1	2	3	4	5	6	7

Milk (cow) & soya (1 glass/200 ml) *(continued)*	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q29p4 Semi-skimmed milk	1	2	3	4	5	6	7
q29p5 Skimmed milk	1	2	3	4	5	6	7
q29p6 Condensed milk	1	2	3	4	5	6	7
q29p7 Total yogurt (any type, on average)	1	2	3	4	5	6	7
q29p8 Greek-style yoghurt	1	2	3	4	5	6	7
q29p9 Fromage frais	1	2	3	4	5	6	7
q29p10 Soya milk (any)	1	2	3	4	5	6	7
q29p11 Viili (yogurt-like fermented milk)	1	2	3	4	5	6	7
q29p12 Tofu	1	2	3	4	5	6	7

30. Cheeses (1 regular piece or spread for 1 slice of bread)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q30p1 Any cheese	1	2	3	4	5	6	7
q30p2 Hard cheeses (e.g. Cheddar)	1	2	3	4	5	6	7
q30p3 Soft cheeses (e.g. Brie, camembert, Philadelphia, tomini, boursault, brinza, chaource, coulommiers, Humboldt fog, kochkase)	1	2	3	4	5	6	7
q30p4 Semi-hard cheeses (e.g. Gouda, Emmental/Edam)	1	2	3	4	5	6	7
q30p5 Cottage cheese (cheese curd) (natural/with scents)	1	2	3	4	5	6	7
q30p6 Hard and semi-hard Greek cheeses (e.g. Kaseri, kefalotiri, Grafiera, Kefalograviera, Ladotiri)	1	2	3	4	5	6	7
q30p7 Fresh cheeses (e.g. Feta, mozzarella, parmesan)	1	2	3	4	5	6	7

31. Other milk products (1 table spoon unless otherwise stated)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q31p1 Ice cream (1 unit)	1	2	3	4	5	6	7
q31p2 Single cream crème	1	2	3	4	5	6	7
q31p3 Crème fraîche	1	2	3	4	5	6	7
a31p4 Sour cream	1	2	3	4	5	6	7
q31p5 Double or clotted cream	1	2	3	4	5	6	7

32. Miscellaneous food (1 medium portion)	Rarely/ Never	1-3 times a month	Once a week	2-4 per week	5-6 per week	Once a day	2+ per day
q32p1 Dressing sauces (e.g. French, Cesar, thousand islands)	1	2	3	4	5	6	7
q32p2 Mayonnaise	1	2	3	4	5	6	7
q32p3 White sauce (e.g. Béchamel)	1	2	3	4	5	6	7
q32p4 Ketchup	1	2	3	4	5	6	7
q32p5 Fresh vegetable or cereal soups (e.g. green/other cabbage soup, gazpacho, legumes/peas soup, tarhana)	1	2	3	4	5	6	7
q32p6 Fresh meat or offal soups (e.g. waterzoo, patsas)	1	2	3	4	5	6	7
q32p7 Pizza (any)	1	2	3	4	5	6	7
q32p8 Moussaka	1	2	3	4	5	6	7

Additional questions:

33. Products for special nutritional use
Do you REGULARLY take any nutritional supplement? e.g. vitamin C, selenium etc?

q33

Yes ☐

No ☐

If you answered yes to question 33, please indicate:

Name of the supplement	**Dose normally taken**	**Times per day dose is taken**	**Times per week dose is taken**
q33p1	**q33p1dose**	**q33p1daily**	**q33p1week**
q33p2	**q33p2dose**	**q33p2daily**	**q33p2week**
q33p3	**q33p3dose**	**q33p3daily**	**q33p3week**
q33p4	**q33p4dose**	**q33p4daily**	**q33p4week**
q33p5	**q33p5dose**	**q33p5daily**	**q33p5week**

34. Are there any other foods you normally eat once or more a week?

q34

Yes ☐

No ☐

If yes, please list below:

Food (if it is a local dish, and you know the main components or ingredients, please name them)	Usual serving size	Number of times eaten per week
q34p1	q34p1size	q34p1times
q34p2	q34p2size	q34p2times
q34p3	q34p3size	q34p3times
q34p4	q34p4size	q34p4times

35. What kind of fat did you most often use for frying, roasting, grilling, etc?

q35 Select one only please:

Butter	1
Lard/dripping	2
Vegetable oil	3
Solid vegetable fat	4
Margarine	5
None	0

36. How often do you add salt to food while cooking?

q36

Always	1
Usually	2
Rarely	3
Sometimes	4
Never	0

37. In the last year, on average, how many times a week did you eat a medium serving (unit/glass or cup) of the following foods?

Food type	Times/month
q37p1 Vegetables (excluding potatoes)	q37p1times
q37p2 Salads	q37p2times
q37p3 Fruits and fruit products (excluding fruit juice)	q37p3times
q37p4 Fish	q37p4times
q37p5 Fish products	q37p5times
q37p6 Meat, meat products or meat dishes (including bacon, ham and chicken)	q37p6times
q37p7 Milk (skimmed, full fat, any)	q37p7times

38. Are there any foods you do not eat because they cause you allergy or intolerance?

q38

Yes ☐ No ☐

If yes, please name these foods below:

Food not consumed	Reason
q38p1	q38p1reason
q38p2	q38p2reason
q38p3	q38p3reason
q38p4	q38p4reason

39. Are you currently following a special diet?

Yes ☐ No ☐

If you answered yes, please indicate if you are following one these diets:

	Yes	No
q39p1 Weight loss	1	2
q39p2 Hypertension	1	2
q39p3 Diabetes Mellitus	1	2
q39p4 Coeliac disease	1	2

40. Please indicate (tick as appropriate) if you suffer any of the following illnesses:

	Yes	No
q40p1 Hypertension	1	2
q40p2 Heart disease (any)	1	2
q40p3 Diabetes Mellitus Type I	1	2
q40p4 Diabetes Mellitus Type II	1	2
q40p5 Obesity/overweight	1	2

41. Please write your weight (kg) and height (mt)

q41p1 Weight:	**q41p2** Height:

THANK YOU FOR YOUR COOPERATION!

Appendix 21 UK Children Consent Form

Subject ID:
Centre No:

Project – **GA²LEN Follow up Study**:
A Europe-wide study to assess the severity and burden of allergic diseases in a European Population.

Chief Investigator: **Professor Peter Burney**

Please initial each box you agree to. Put a line through any box you do not agree to.

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my child's participation is voluntary and that they are free to withdraw at any time, without giving a reason. ☐

3. I give permission for their GP to be informed that I have agreed for my child to take part in this study. ☐

4. I understand that a sample of my child DNA will be stored and analysed as part of this study. ☐

5. I agree that the study researchers may store my child DNA and analyse it again at a later date. It will be looked at specifically for research into asthma, allergic disorders, other respiratory disease and sinusitis and will not be used for any other purpose. ☐

6. I understand that some serum of my children will be stored anonymously and indefinitely for future analyses and I agree that the study researchers may store these samples and analyse it again at a later date. It will be looked at specifically for research into asthma and allergy and will not be used for any other purpose. ☐

7. I am happy for any residual blood to be used in any future research into asthma and allergy ☐

8. I agree for my child to take part in the study. ☐

Name of Parent or Guardian	Date	Signature
		Childs Name
Researcher	**Date**	**Signature**

Version 1

Appendix 22 WOMEN'S QUESTIONNAIRE

This questionnaire is specifically designed to get information about women and their hormones.

If you do not wish to answer some of the questions leave them blank and tell the nurse at the clinic you prefer not to answer them.

Some of the questions may seem to repeat questions that have been asked earlier. This is necessary to get the full picture of your hormonal status.

Place barcode sticker here……..……

1. What is today's date? DAY ☐☐ MONTH ☐☐ YEAR ☐☐

2. How old were you when you had your first period? YEARS ☐☐
(**If not yet started enter 88**)

3. Are you currently pregnant? NO ☐ YES ☐

If YES go straight to QUESTION 11. **If NO go to QUESTION 4**

4. Are you currently taking a hormonal treatment to HELP you get pregnant? NO ☐ YES ☐

If YES go straight to QUESTION 11. **If NO go to QUESTION 5**

5. Have you **ever** had a hysterectomy (your womb removed)? NO ☐ YES ☐

If NO go straight to QUESTION 6. **If YES answer all of QUESTION 5**

5.1 How old were you when you had a hysterectomy? YEARS ☐☐

5.2 What was the **MAIN** reason for having your womb removed? TICK ONE BOX ONLY
- a) Heavy or painful or irregular periods a ☐
- b) Heavy or painful or irregular periods associated with fibroids b ☐
- c) Growths inside the womb that were not fibroids c ☐
- d) Prolapse d ☐
- e) Don't know e ☐
- f) Other – please describe_____ f ☐

5.3 How old were you when these symptoms (from answer to q5.2) began? YEARS ☐☐

5.4 How many ovaries were removed at the time of your hysterectomy? TICK ONE BOX ONLY
- a) None a ☐
- b) One b ☐
- c) Both c ☐
- d) Don't Know d ☐

6 . How many periods have you had in the last 12 months? NUMBER ☐☐

IF PERIODS IN THE LAST 12 MONTHS – answer all of QUESTION 6 and then go to QUESTION 8

IF NO PERIODS IN THE LAST 12 MONTHS – go straight to QUESTION 7

For women with periods in the last 12 months

Please think back to your most recent menstrual period.

6.1.1. What was the date of the first day of your last menstrual period? DAY ☐☐ MONTH ☐☐ YEAR ☐☐

6.1.2. How many days were there between your most recent period and the period before it? DAYS ☐☐☐
(Count from the first day of one bleeding period to the first day of the next bleeding period)

6.1.3 Are your periods regular? TICK ONE BOX ONLY

a) Yes	a	☐
b) No they have never been regular	b	☐
c) No they have been irregular for a few months	c	☐

6.1.4 Over the last 12 months what was the usual interval between your periods? TICK ONE BOX ONLY

a) Less than 24 days	a	☐
b) 24-26 days	b	☐
c) 27-29 days	c	☐
d) 30-32 days	d	☐
e) More than 32 days	e	☐

6.1.5 Is your menstrual cycle often (over twice a year) more than 35 days? NO ☐ YES ☐

6.1.6 Over the last 12 months what was the shortest cycle length? DAYS ☐☐
6.1.7. Over the last 12 months what was the longest cycle length? ☐☐
(A cycle length is the number of days from the first day of one bleeding period to the first day of the next bleeding period)

6.1.8 Have you experienced changes in the number of days or amount of bleeding you have with your menstrual cycles during the past 5 years? NO ☐ YES ☐

6.1.9 During the past 5 years, have you experienced changes in the length of your menstrual cycle (that is, the number of days from one period to the next)? NO ☐ YES ☐

NOW GO TO QUESTION 8

For women with no periods in the last 12 months

7. 0 How old were you when you had your last period? YEARS ☐☐

7.1 What statement best describes the reason you have not had a period in the last 12 months -

		TICK ONE BOX ONLY
a) My periods have stopped because of the menopause	a	☐
b) My periods have stopped because I had a hysterectomy	b	☐
c) My periods stopped because I had my ovaries removed	c	☐
d) I have been pregnant or breast feeding in the last 12 months	d	☐
e) I have been taking treatments that affect my periods	e	☐
f) My periods stopped because I have been unwell	f	☐
g) My periods have never started	g	☐
h) None of the above – please describe_____	h	☐

8 Some women experience hot flushes/flashes or night sweats as they approach menopause, even when they are still having menstrual cycles. Have you **ever** had either of these symptoms at a time which could be related to menopause?

TICK ONE BOX ONLY

a) No	a	☐
b) Yes	b	☐
c) Maybe	c	☐

If NO go straight to QUESTION 9. If YES or MAY BE go to QUESTION 8.1

TICK ONE BOX ONLY

8.1 How often have you had hot flashes and/or night sweats **in the past 6 months?**

a) Not at all	a	☐
b) Less than once per week	b	☐
c) More than once a week but not every day	c	☐
d) Every day	d	☐

NO ☐ YES ☐

9. Have you **ever** taken a treatment which contains hormones to stop you getting pregnant (includes tablets eg: *'the pill'*, depot injection, coil with hormone impregnated eg Mirena)?

If NO go straight to QUESTION 10, If YES go to question 9.1

YEARS

9.1 How old were you when you first took a treatment which contains hormones to stop you getting pregnant? ☐☐

YEARS

9.2 How old were you when you last took a treatment which contains hormones to stop you getting pregnant (includes tablets, depot injection, coil with hormone impregnated e.g. Mirena)? ☐☐

9.3. How many years in **total** have you taken or used the following

YEARS

a) the 'pill'	☐☐
b) injections to stop you getting pregnant	☐☐
a) coil impregnated with hormones	☐☐

*(if you have taken then off and on over the years as you had your family please provide an estimate of the **TOTAL** years taken)*

NO ☐ YES ☐

9.4 Are you **currently** taking a treatment which contains hormones to stop you getting pregnant (includes tablets, depot injection, coil with hormone impregnated e.g. Mirena)?

If NO go straight to QUESTION 10. If YES answer the rest of QUESTION 9

9.4.1What is the name of the medication you are currently taking? (free text with later coding) ☐☐

……

YEARS

9.4.2 How many years in **total** did you take this particular medication? ☐☐

NO ☐ YES ☐

10. Have you **ever** taken a treatment which contains hormones to reduce the symptoms or effects of the menopause (includes *'HRT'* tablets, depot injection, patches, gels but not vaginal CREAMS or pessaries)?

If NO go straight to QUESTION 11; If YES go to QUESTION 10.1

YEARS

10.1 How old were you when you first took a treatment which contains hormones to reduce the symptoms or effects of the menopause (includes *'HRT'* tablets, depot injection, patches, gels but not vaginal CREAMS or pessaries)??

10.2 At the time you started to take this medication, how often were you having menstrual periods?

TICK ONE BOX ONLY

a) I had not had a period for 12 or more months a
b) I had had at least one period in the previous 12 months, but my cycles had become irregular b
c) My periods were regular during the previous 12 months c

10.3 At the time you started this treatment were you experiencing any of the following symptoms?

		NO	YES
a) hot flushes and/or night sweats	a		
b) palpitations	b		
c) joint aches	c		
d) problems with memory or concentration	d		

YEARS

10.4 How old were you when you last took a treatment which contains hormones to reduce the symptoms or effects of the menopause (includes tablets, depot injection, patches but not CREAMS)?

NO YES

10.5 Are you **currently** taking a treatment which contains hormones to reduce the symptoms or effects of the menopause (includes tablets, depot injection, patches but not CREAMS)?

If NO go to straight to QUESTION 11. If YES answer the rest of QUESTION 10

10.5.1 What is the name of this medication? (free text with later coding)

……

YEARS

10.5.2 How many years in **total** did you take this particular medication?

11. What statement best describes your current situation regarding having a family?

TICK ONE BOX ONLY

a) I have never tried to start a family a
b) I am trying to get pregnant for the first time b
c) I have been pregnant one or more times naturally c
d) I have only been pregnant following fertility treatment d
e) I have been told that I have a medical problem that prevents me from getting pregnant e
f) I have been advised that I have a medical problem that would make it dangerous for me to get pregnant f
g) None of the above – please describe_____ g

If you have NOT HAD A FAMILY go straight to questions 12.

11.1 If you have had a family - please give the year in which each of your children were born and tick the box to indicate whether the child was boy or a girl

Child	Year of birth		Boy		Girl
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

12. Have you ever been told by a doctor that you had endometriosis? NO ☐ YES ☐

If NO go straight to QUESTION 13; If YES go to QUESTION 12.1

12.1 How old were you when you were first had symptoms of endometriosis? YEARS ☐☐

12.2 Did you **ever** take tablets for the treatment of endometriosis? NO ☐ YES ☐

13. Have you ever been told by a doctor that you had a cyst or cysts on your ovaries? NO ☐ YES ☐
If NO go straight to QUESTION 14; If YES go to QUESTION 13.1

13.1 Did you have a **single** cyst? NO ☐ YES ☐
If YES go straight to QUESTION 14; If NO go to QUESTION 13.2

13.2. Has a doctor **ever** told you that you have 'polycystic ovaries'? NO ☐ YES ☐
If NO go straight to QUESTION 14; If YES go to question 13.4

13.3 How old were you when the doctor told you this? YEARS ☐☐

13.4. Did you **ever** take tablets for the treatment of 'polycystic ovaries'? NO ☐ YES ☐

14. Have you ever had acne? NO ☐ YES ☐
IF NO - YOU HAVE FINISHED THE QUESTIONNAIRE. If yes go to question 14.1

14.1 Did you ever have **hormonal** treatment for your acne? NO ☐ YES ☐

Thank you for completing this questionnaire

NURSE AT CLINIC

Please check that the participant has completed the questionnaire as much as they wish to.

Ask the participant
'Have you completed the women's questionnaire?'

'Were there any questions you would like me to help you complete?'

If no – assess the questionnaire responses and make sure the participant has followed the skips correctly.

Specifically

a) Check that question 2 has been completed (if not started enter 88)

b) Check the **LAST DAY OF MENSTRUAL PERIOD (Q6.1.1**) or **AGE AT LAST PERIOD (Q 7)** has been completed

c) Make sure you can read the free text answers to:
9.4.1
10.4.1

Give all menstruating, non-pregnant women who are not on hormonal fertility treatment a postcard to complete and return to your office when they have started their next period.

WORDING FOR 'FREEPOST' CARD TO BE GIVEN TO MENSTRUATING, NON-PREGNANT WOMEN WHO ARE NOT ON HORMONAL FERTILITY TREATMENTS

GA^{2}LEN Women's Study Centre number
Id number

Please return this card on the first day of you next period giving the date.

I attended the GA^{2}LEN survey on

DAY			**MONTH**			**YEAR**	

The first period I had since my visit started on

DAY			**MONTH**			**YEAR**	

Thank you for your help with this study

Instructions for Women's Questionnaire

One of the aims of the survey is to assess the association of use of exogenous hormones (oral contraceptives pills, hormones replacement therapy) and endogenous hormone level with allergy and allergic diseases.

A questionnaire to collect relevant information has been developed. This is referred to as the WOMEN'S QUESTIONNAIRE.

The WOMENS QUESTIONNAIRE should be sent to participants and they should be asked to complete it at home the day prior to attending.

At the clinic interview the fieldworker should check that there have been no problems completing it. Women who have not completed it should be asked to fill one in while they are at the clinic.

Ask the participant
'Have you completed the women's questionnaire?'

'Were there any questions you would like me to help you complete?'

If no – assess the questionnaire responses and make sure the participant has followed the skips correctly.

Specifically
a) Check the date on which the questionnaire was completed.

b) Check that question 2 has been completed (if not started enter 88)

c) Check the **LAST DAY OF MENSTRUAL PERIOD (Q6.1.1**) or **AGE AT LAST PERIOD (Q 7)** has been completed

d) Make sure you can read the free text answers to:
9.4.1
10.4.1

The following instructions should help you respond to any queries the woman may have experienced completing the questionnaire

In general when women are asked for an age at which something happened or for the number of years they have taken treatment some may say that 'do not remember'. A 'best guess' is better than no answer at all.

Question 1
One of the overarching aims of this study is to obtain **phase in cycle** of women pre/peri-menopausal women. It is essential that correct information on the date the questionnaire is completed is available.

Question 2
Enter 88 if not yet started

Question 3
Women who are currently pregnant need only answer questions 1-3 and 11-14. A woman is considered to be pregnant if she believes herself to be pregnant.

Question 4
Women who are taking hormonal fertility treatment or undergoing IVF treatment need only answer questions 1-4 and 11-14.

Question 5
If a women does not know if she has had a hysterectomy the answer is **NO**.

5.2 Some women may have had multiple reasons why they had a hysterectomy eg: prolapse and painful periods. Please ask them to give the **main** reason. It is unlikely that women will have had a hysterectomy for ASYMPTOMATIC fibroids. If this is the case enter this cause under OTHER.
5.4 Women should chose one option from the four given

Question 6
These questions are to assess whether women are pre/peri/post menopausal and where they are in their current menstrual cycle. Women should state the number of periods they have had in the last 12 months. A period may be considered a period even if it is in response to withdrawal bleeds occurring as a result of the pill or HRT. Women who have had no periods in the last year should complete question 7. Those who have had periods complete question 6.

6.1.1 It is important that this date is as accurate as possible
6.1.2 Women should count from the first day of one bleeding period to the first day of the next
6.1.3 'Regular' means that 'each cycle is of similar length and is predictable'.
6.1.4 The length of time refers to the number of days from the first day of one period to the first day of the next. 'Usual' means the number of days between periods that has occurred the most often in the last 12 months. Women with very irregular periods may find this difficult to answer – even so they should give their 'best guess.'
6.1.5 Thirty five days refers to the number of days from the first day of one period to the first day of the next.
6.1.6 The question refers to the number of days from the first day of one period to the first day of the next
6.1.7 The question refers to the number of days from the first day of one period to the first day of the next
6.1.8 The questions refers to the length of the menstrual bleed and the amount – changes imply, but do not diagnose, entry into the peri-menopause
6.1.9 The question refers to the length of the cycle (the number of days from the first day of one period to the first day of the next).

Question 7
This question should be completed by women who have had no periods in the last 12 months**.**

7.1. Most women will remember this. Much older women may find it more difficult to remember. A 'best guess' should be made if the participant cannot remember precisely.
7.2 Women should identify one reason for their periods ending. If none of the reasons given explain the end of menstruation a free text answer should be provided.

Question 8
The aim of this question is to help identify women who are peri/post menopause.

Question 9

The aim of this question is to identify women who have taken hormonal contraceptives. Contraceptive pills are broadly divided into **LOW DOSE**, **STANDARD DOSE** and **PROGESTERONE** ONLY. Other treatments include **LOW DOSE PATCH**, **PROGESTERONE IMPLANTS** and **INJECTIONS** and **PROGESTERONE INTRA-UTERINE DEVICES**. Most women, if they have taken any hormonal contraceptives will have taken '*the pill*' but there are other treatments available. Some of the older women in the study may think this question is not relevant to them. They should however still answer the question.

9.2 Many women can remember the age they last used a contraceptive. A 'best guess' should be made if they cannot remember precisely. If they are currently taking hormonal contraceptives then they should give their current age.

9.3. The aim is to know how many years women took hormonal contraceptives. The difficulty is that they may have taken the treatment off and on over the years as they have had their family. Women should provide an estimate of the **total** number of years they have actually taken hormonal contraceptives, allowing for these gaps. *(For example if they took the pill from ages 16 to 24 and then from 30-35 the total years = 13 years)*

9.4.1 The treatment should be written clearly and coded later (see below)

9.4.2 The aim is to know how many years women took this particular medication. The difficulty is that they may have taken the treatment off and on over the years as they have had their family. Women should provide an estimate of the total number of years they have actually taken hormonal contraceptives, allowing for these gaps. *(For example if they took this particular medication from ages 16 to 24 and then from 30-35 the total years = 13 years. We are only interested in this particular tablet that they have described, not years taking a different one)*

Question 10

The aim of this question is to identify women who have taken hormonal replacement therapy for symptoms (any symptoms including osteoporosis) related to the menopause. We are only interested in treatment that is HORMONES or INFLUENCE HORMONAL STATUS.

HRT treatments are available as tablets, pills, patches or patches with tablets. There are some GELS that are spread over an area of the body such as the arms and are equivalent to a PATCH. There are also vaginal creams and pessaries that are local treatments for localised symptoms. For the purpose of this questionnaire a woman who has only taken local vaginal creams/pessaries is not considered to have had HRT treatment. She should answer **NO** to question 10. A woman who has used GELS should answer **YES**.

Nasal sprays for the treatment of menopause are also available.

10.3 We want to know whether women started taking this treatment when they were peri/post-menopausal. It is common for women to start these treatments even when they are still having periods.

a. The aim is to know what symptoms women were experiencing at the time they started taking HRT. Some women may have had no symptoms but were advised to take it by their doctor.

i. The treatment should be written clearly and coded later (see below)

10.5.2 The aim is to know how many years women took this particular medication. The difficulty is that they may have taken the treatment off and on over the years. Women should provide an estimate of the total number of years they have actually taken this particular medication. *(For example if they took this medication from ages 45-50 and then from 52-55 the total years = 7 years)*

Question 11
Women should select the one that best describes their situation. If a woman is currently pregnant the answer should be either **c** or **d**

11.1 The participants should give the year of birth of each live birth they have had. They should only record LIVE BIRTHS. Be sensitive to the distress this question could cause some women, and be aware that some may not wish to complete it.

Question 12
The answer to this question should be yes only if the woman has been told by a doctor she has endometriosis.

Question 13
Women should only answer YES if a doctor has told them they have a cyst or cysts on their ovaries.

13.1 Some women may have had only one cyst. This may have got better on its own OR following specific treatment. These women should answer 'yes' to this question and then go on to question 14.

Question 14
The term acne implies the presence of plugged pores (blackheads and whiteheads), pimples, and even deeper lumps (cysts or nodules) that occur on the face, neck, chest, back, shoulders and even the upper arms – more than is usual. To some extent many teenagers have problems with pimples and blackheads. The participant should answer this question without prompts from the interviewer. If they 'don't know' the answer is NO.

Finding out date of next period.
At the end of the interview women who have had a period in the last 12 months, are not pregnant, and are not taking fertility treatments, should be given a small stamped card addressed back to the research team. The team should ask the woman to complete and return this when their next period starts. This is an important step in assessing phase in cycle. Women who forget to return the postcard should be phoned to find out the date of their next menstrual period.

GA^{2}LEN Women's Study Centre number
Id number

Please return this card on the first day of you next period giving the date.

I attended the GA^{2}LEN survey on

DAY			**MONTH**			**YEAR**	

The first period I had since my visit started on

DAY			**MONTH**			**YEAR**	

Thank you for your help with this study

Coding of hormonal treatments

The coding of hormonal treatments is complex due to the wide variety of medications available and the variations in medications available in Europe. Many of the hormonal medications can be used for different conditions.

The SAME coding system is used for all questions related to medication usage in the WOMENS QUESTIONNAIRE.

Question 9
Contraceptive pills are broadly divided into **LOW DOSE**, **STANDARD DOSE** and **PROGESTERONE** ONLY. Other treatments include **LOW DOSE PATCH**, **PROGESTERONE IMPLANTS** and **INJECTIONS** and **PROGESTERONE INTRA-UTERINE DEVICES**.

Question 10
Treatments for menopause are more complex. Indeed some women may report they are taking a pill that is also used for oral contraception as a treatment for menopause. However HRT treatments are different. For example some treatments use **CONJUGATED OESTROGENS**, and other use **ESTRADIOL**. Ethinylestradiol (which is normally used for contraceptive purposes) is not generally used for HRT – although it is possible that some women may believe it prescribed for menopause.

Women who have had a hysterectomy will mainly be taking HRT treatments that contain an **OESTROGEN ONLY**. Others will take HRT that contains **OESTROGENS WITH PROGESTERONES**. Treatments are available as **TABLETS, PATCHES, PATCHES USED IN COMBINATION WITH TABLETS, GELS** and **NASAL SPRAYS**.

Question 12
Treatments for endometriosis may include the use of **COMBINED ORAL CONTRACEPTIVE, PROGESTERONE ONLY TREATMENTS, DANAZOL, GESTRINONE** and **GONADOTROPHIN RELEASING HORMONE ANALOGUES** (which may also be taken with HRT treatments).

Question 13
Treatments for polycystic ovary syndrome will include **COMBINED ORAL CONTRACEPTIVE**, **PROGESTERONE ONLY TREATMENTS**, **GONADOTROPHIN RELEASING HORMONE ANALOGUES** and **INSULIN SENSITISING AGENTS**. Some women will take **CLOMIPHEN** to treat the infertility associated with their PCOS, others may take **SPIRONOLACTONE** for the acne associated with their PCOS.

Question 14
Treatments for acne may include the **COMBINED ORAL CONTRACEPTIVE** or a specific medication containing **CYPROTERONE ACETATE** (which is combined with an oestrogen in order to ensure no pregnancy occurs while taking the medication). Other treatments reported may include daily antibiotics but these are not hormonal treatments and the subject should respond NO.

The coding system provided covers most common medication combinations. If a woman reports a medication that cannot be coded please immediately e-mail d.jarvis@imperial.ac.uk giving the email the heading CODING QUERY and providing all the information you have on the treatment. Dr Jarvis will then specify the code you should use. All centres will then be informed of the additional codes.

For all other queries regarding the conduct of the Women's Questionnaire –please contact d.jarvis@imperial.ac.uk giving the email the heading WOMEN GALEN QUERY.

Coding for treatments in women's questionnaire

Mainly as contraceptives

	Low strength pill (oral)	Ingredient 1		Ingredient 2		Comment
1	**Loestrin 20**	ethinylestradiol	≤20 micrograms	norethisterone	≤1 mg	
2	**Mercilon**	ethinylestradiol	≤20 micrograms.	desogestrel	≤150 micrograms	
3	**Femodette** **Sunya 20/75**	ethinylestradiol	≤20 micrograms	gestodene	≤75 microgram	
	Low strength (transdermal)					
5	**Evra**	ethinylestradiol	≤20 micrograms	norelgestromin	≤150 micrograms	Dose per 24 hours
	Standard strength (oral)					
10	**Logynon** **Logynon ED** **Microgynon 30** **Micrgynon 30 ED** **Ovranette** **Trinordial**	Ethinylestradiol		levonorgestrel		
11	**Binovum** **Brevinor** **Loestrin 30** **Norimin** **Ovysmen** **Synphase** **Trinovum**	Ethinylestradiol		Norethisterone		
12	**Cilest**	Ethinylestradiol		Norgestimate		
13	**Marvelon**	Ethinylestradiol		Desogestrel		
14	**Yasmin**	Ethinylestradiol		Drospirenone		
15	**Femodene** **Femodene ED** **Katya 30/75** **Triadene**	Ethinylestradiol		Gestodene		
16	**Norinyl**	Mestranol		Norethisterone		

Coding for treatments in women's questionnaire

Mainly as contraceptives

	Progesterone only (oral)	Ingredient 1		Ingredient 2		Comment
25	**Cerazette**			Desogestrel		
26	**Femulen**			etynodiol diacetate		
27	**Micronor** **Noriday**			norethisterone		
28	**Norgeston**			levonorgestrel		
	Progesterone only (parenteral)					
35	**Depo-provera**			medroxyprogesterone acetate		Injection lasts ~ 12 weeks
36	**Noristerat**			norethisterone enantate		Injection lasts ~ 8 weeks
37	**Implanon**			etonogestrel		IMPLANT lasts ~ 3 yrs
	Progesterone only – intra-uterine					
40	**Mirena**			levonorgestrol		IUD effective 5 years

Coding for treatments in women's questionnaire

Mainly as treatments for menopause

	Oral HRT (oestrogen + progesterone)	Ingredient 1		Ingredient 2		Comment
50	**Premique**	Conjugated oestrogen		medroxyprogesterone		
51	**Prempak C**	Conjugated oestrogen		norgestrel		
52	**Climesse** **Nuvelle Continuous** **Trisequens** **Trisequens forte** **Elleste-Duet** **Kliofem** **kliovance**	Estradiol (valerate)		Norethisterone (acetate)		
53	**Cylco-progynova** **nuvelle**	Estradiol (valerate)		levornorgestrel		
54	**Femoston**	estradiol		dydrogesterone		
55	**Estra**	estradiol		medroxyprogeterone		
	HRT patches (oestrogen + progesterone)					
60	**Estracombi** **Estrapak 50** **Evorel Sequi**	estradiol		Norethisterone (acetate)		Patch
61	**Femapak**	estradiol		dydrogesterone		Patch
62	**Nuvelle TS**	estradiol		levonorgestrel		Patch
	Conjugated oestrogen only					
65	**Premarin**	Conjugated oestrogen				

Coding for treatments in women's questionnaire

Mainly as treatments for menopause

	Estradiol only	Ingredient 1		Ingredient 2		Comment
70	**Estradiol Implants**	Estradiol				IMPLANT -
71	**Climaval** **Elleste Solo** **Progynova** **Zumenon**	Estradiol (valearate)				TABLETS
72	**Dermestril** **Elleste Solo MX** **Estraderm MX** **Estraderm TTS** **Evorel** **Fematrix** **FemSeven** **Menorest** **Progynova TS**	estradiol				PATCHES
73	**Oestrogel** **Sandrena**	estradiol				GELS spread over large area – **not** local creams applied to vaginal area
	Estradiol, estrione, estrone only					
75	**Hormonin**	Estradiol, estrione, estrone				
	Estriol only					
76	**Ovestin**	Estriol				
	Estropiapte only					
77	**Harmogen**	Estropipate				
	Tibolone					
78	**Tibolone**	tibolone				
	Raloxifen					
79	**Evista**	raloxifene hydrochloride				

When treatment unknown

	Other					
98	***Took a tablet but participants cannot remember the name or fieldworker cannot find any details on the medication within the tablet***					

Appendix 23 Spirometry Safety Questions

1. In the past three months have you had any surgery on your chest or abdomen? Yes □ 1 No □ 2

2. Have you had a heart attack within the past three months? Yes □ 1 No □ 2

3. Do you have a detached retina or have you had eye surgery within the past three months? Yes □ 1 No □ 2

4. Have you been hospitalized for any other heart problem within the past month? Yes □ 1 No □ 2

5. Are you in the last trimester of pregnancy? Yes □ 1 No □ 2

6. Does the participant have a resting pulse of greater than 120 beats per minute? Yes □ 1 No □ 2

7. Is the participant currently taking medication for tuberculosis? Yes □ 1 No □ 2

*If the participant answers "Yes" to any of Questions 1 through 7, do **NOT** proceed with the test.*

8. Have you had a respiratory infection (cold) in the last three weeks? Yes □ 1 No □ 2

9. Have you used any medication for breathing in the last three hours? Yes □ 1 No □ 2

10. Spirometry Outcome

Pre-bronchodilator test completed? Yes □ 1 No □ 2

Post-bronchodilator test completed? Yes □ 1 No □ 2

Unable to obtain satisfactory spirometry (check one)
The participant did not understand instructions □ 2
The participant was medically excluded □ 3
The participant was unable to physically cooperate □ 4
The participant refused □ 5

11. Did the participant experience any adverse events as a result of performing the spirometry test? Yes □ 1 No □ 2

If yes, please briefly describe event:

_____

_____

12. Please note any items about the spirometry test concerning the ability of the participant to adequately perform the manoeuvre (e.g. kyphosis, dentures, missing limbs, etc.).

_____

_____

Appendix 24 GP results report form

Imperial College London
Respiratory Epidemiology & Public Health
National Heart and Lung Institute
RBH Campus
Emmanuel Kaye Building
Manresa Road
London SW3 6LR

Tel: 44 207-3528121 extn 3506
Fax: 44 2073518322

Head of Unit
Professor Peter Burney
MA MD FRCP FFPH FMedSci
Email:p.burney@imperial.ac.uk

Re: **Ethics Committee Ref: 08/H0718-33**

Dear Doctor ……

Re: **GA²LEN Follow Up Study**

Your patient…….. recently took part in the GA2LEN Follow Up Study. This study is part of an international research programme that aims to investigate the causes of asthma and allergies and included participants with and without asthma and allergies.

As part of this survey, we have conducted post bronchodilator spirometry and skin prick tests.
The participant has requested the result of the spirometry and skin tests to be forwarded to you.

Test	Pre	post	% predicted value
FEV1			
FEV1/FVC			
FVC			
% reversibility of FEV1			

These values were recorded using the ndd EasyOne™ Spirometer based on American Thoracic Society guidelines.

Please contact Miss Mun Lim, who is coordinating this study, on telephone number 020-73528121 ext 3503 email: m.lim@imperial.ac.uk

We have also attached the results of other tests conducted during the study.

Thank You.

Yours sincerely,

Professor Peter Burney
Professor of Respiratory Epidemiology
& Public Health
Imperial College London

Dr Nada Lemic
Consultant in Public Health
Bromley Primary Care Trust

Allergy Skin Tests

When tested with the following allergens (xxxx,xxxx,xxxx) your patient showed a wheal size of 3mm or greater to the following allergens

About one in three adults in the UK have a positive skin test result to one or more common allergens. If your patient has asthma, hay fever or any other allergic condition a positive test may shed some light on the triggers to their symptoms but this can only be assessed with a full clinical history. As with all tests, skin tests are subject to false positives and false negatives.

Appendix 25

Participant Tracking Form
GA²LEN Survey Follow Up Study

Barcode Sticker

Data Collection Items	Yes	No
Informed Consent Form		
Main Questionnaire		
EuroQoL Questionnaire		
Food Frequency Questionnaire		
Women's Questionnaire		
Spirometry Safety Questionnaire		
Maximum Post bronchodilator Test Result		
Allergy Skin Prick Test Result		
Smell Test Result		
PNIF Test Result		
Blood Samples		
Age Gender F / M **delete as appropriate** **Date of Visit** **Response Code**		

1	Responded
2	Refused
3	Known to have moved or address unknown
4	No response after 3 mail out
5	Other (deceased)

Study Staff: _____
Title of Study Staff:_____
Study Staff Code_____